IMNOVID®▼ (pomalidomide)

Healthcare Professional's Information Pack

UK

Version 2

Important Safety Information:
Healthcare Professionals involved in the prescribing or dispensing of pomalidomide must read and understand the information contained within this pack.
For complete safety information please refer to the Summary of Product Characteristics for pomalidomide, available at the UK electronic medicines compendium (emc) website: www.medicines.org.uk.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.

Healthcare professionals are asked to report any suspected adverse reactions using the Yellow Card Scheme via www.mhra.gov.uk/yellowcard or by searching for MHRA Yellow Card in the Google Play or Apple App Store. Adverse reactions should also be reported to Originalis Medical Information on +44 (0)203 630 1244 or MedInfo@originalis.eu).

Originalis

Date of preparation of text: May 2022
RMP/Originalis/Imnovid/UK/002/0522
Approved by MHRA:

IMNOVID®▼ (pomalidomide)

Healthcare Professional's Information Pack
UK

This pack contains the information and materials needed for the prescribing and dispensing of pomalidomide, including information about the Pregnancy Prevention Programme.

It is a requirement of the Pregnancy Prevention Programme that all healthcare professionals ensure that they have read and understood this pack before prescribing or dispensing pomalidomide for ANY patient.

An easy reference guide is included at the back of your pack. This summarises the information for ongoing patient safety and the main steps in the IMNOVID Pregnancy Prevention Programme process.

Pomalidomide is indicated:

- In combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior treatment regiment including lenalidomide.

- In combination with dexamethasone for the treatment of adult patients with relapsed and refractory multiple myeloma (MM) who have received at least two prior treatments regimens, including both lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy.

When pomalidomide is given in combination with other medicinal products, the corresponding SmPC must be consulted prior to treatment.

Pomalidomide is structurally related to thalidomide. Thalidomide is a known human teratogen that causes severe life-threatening birth defects. Pomalidomide was found to be teratogenic in both rats and rabbits when administered during the period of major organogenesis.

If pomalidomide is taken during pregnancy, a teratogenic effect of pomalidomide in humans is expected. Pomalidomide is therefore contraindicated in pregnancy and in women of childbearing potential unless the conditions of the Pregnancy Prevention Programme in this pack are carried out.

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IMNOVID®▼ (pomalidomide)

Pregnancy Prevention Programme

Information for Healthcare Professionals

Prescribing or Dispensing Pomalidomide

UK

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.

Healthcare professionals are asked to report any suspected adverse reactions using the Yellow Card Scheme via www.mhra.gov.uk/yellowcard or by searching for MHRA Yellow Card in the Google Play or Apple App Store. Adverse reactions should also be reported to Originalis.

Originalis contact details:

Diamantweg 4 - 1812RC,
Alkmaar – The Netherlands
Phone: +44 (0)203 630 1688
Email: CustomerServices@Originalis.eu

Date of preparation of text: May 2022
RMP/Originalis/Imnovid/UK/002/0522
Approved by MHRA:

This brochure contains the information needed for prescribing and dispensing pomalidomide, including information about the Pregnancy Prevention Programme (PPP). Please also refer to the Summary of Product Characteristics (SmPC), which can be found on the emc website: www.medicines.org.uk, for further information.

IMNOVID Pregnancy Prevention Programme:

If pomalidomide is taken during pregnancy it can cause severe birth defects or death to an unborn baby. This Programme is designed to make sure that unborn babies are not exposed to pomalidomide. It will provide you with information about how to follow the programme and explain your responsibilities.

Other side effects of pomalidomide:

A full list of all side effects, further information and recommended precautions can be found in the IMNOVID SmPC.

Important information about the safe disposal of unwanted capsules and restrictions on donating blood during treatment is also included in this brochure.

This brochure will help you understand these problems and make sure you know what to do before prescribing and dispensing pomalidomide.

For your patient's health and safety, please read this brochure carefully. You must ensure that your patients fully understand what you have told them about pomalidomide and that they have provided written confirmation on the Treatment Initiation Form, before starting treatment.

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Contents

Date of preparation of text: May 2022 RMP/Originalis/Imnovid/UK/002/0522 Approved by MHRA:

1.0 Introduction

1.1 Licensed Indications

Pomalidomide in combination with bortezomib and dexamethasone is indicated in the treatment of adult patients with multiple myeloma who have received at least one prior treatment regimen including lenalidomide.

For this indication, the recommended starting dose of pomalidomide is 4 mg orally once daily on Days 1 to 14 of repeated 21-day cycles. Pomalidomide is administered in combination with bortezomib and dexamethasone. The recommended starting dose of bortezomib is 1.3 mg/m^2 intravenous or subcutaneous once daily, on the days shown in Table 1 in Section 4.2 of the SmPC. The recommended dose of dexamethasone is 20 mg orally once daily, on the days shown in Table 1 in Section 4.2 of the SmPC. Treatment with pomalidomide combined with bortezomib and dexamethasone should be given until disease progression or until unacceptable toxicity occurs.

For patients >75 years of age, the starting dose of dexamethasone is 10 mg once daily on Days 1, 2, 4, 5, 8, 9, 11 and 12 of each 21-day cycle for Cycles 1 to 8 and 10 mg once daily on Days 1, 2, 8 and 9 of each 21-day cycle for Cycles 9 and onwards. No dose adjustment is required for pomalidomide. For bortezomib, refer to the current SmPC for additional information.

Pomalidomide in combination with dexamethasone is indicated in the treatment of adult patients with relapsed and refractory multiple myeloma (MM) who have received at least two prior treatment regimens, including both lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy.

For this indication, the recommended starting dose of pomalidomide is 4 mg orally once daily on Days 1 to 21 of repeated 28-day cycles (21/28-days). The recommended dose of dexamethasone is 40 mg orally once daily on Days 1, 8, 15 and 22 of each 28-day treatment cycle. Treatment with pomalidomide combined with dexamethasone should be given until disease progression or until unacceptable toxicity occurs.

For patients >75 years of age, the starting dose of dexamethasone is 20 mg once daily on Days 1, 8, 15 and 22 of each 28-day treatment cycle. No dose adjustment is required for pomalidomide.

For full details, please refer to the SmPC, which can be found on the emc website www.medicines.org.uk.

When pomalidomide is given in combination with other medicinal products, the corresponding SmPC must be consulted prior to treatment.

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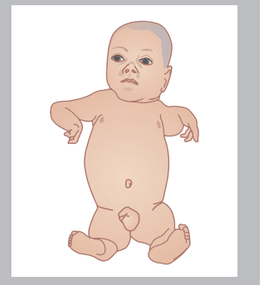
1.2 Summary of the IMNOVID Pregnancy Prevention Programme

This brochure contains the information needed for the prescribing and dispensing of pomalidomide including information about the Pregnancy Prevention Programme.

Pomalidomide is structurally related to thalidomide, a known human teratogenic substance that causes severe life-threatening birth defects. Pomalidomide induced, in rats and rabbits, malformations similar to those described with thalidomide.

If pomalidomide is taken during pregnancy, a teratogenic effect of pomalidomide in humans is expected. Pomalidomide is therefore contraindicated in pregnancy and in women of childbearing potential unless the conditions of the Pregnancy Prevention Programme are met (please refer to sections 4.4 and 4.6 of the SmPC for further details).



- All men and all women of childbearing potential should undergo, at treatment initiation, counselling of the need to avoid pregnancy (this must be documented via a Treatment Initiation Form and checklists for counselling are provided)
- Patients should be capable of complying with the requirements of safe use and handling of pomalidomide
- Patients must be provided with a copy of the Patient Brochure and Patient Pocket Information Card.

In order to obtain pomalidomide, it is a requirement of the Pregnancy Prevention Programme that all healthcare professionals ensure that they have read and understood the information provided in this pack before prescribing or dispensing pomalidomide for any patient.

- Prescribers must complete the appropriate Treatment Initiation Form with every patient before the first prescription is issued
- Pharmacies must register with Originalis to be able to order and dispense pomalidomide. To do this, the pharmacist must use the paper Pharmacy Registration Form
- Every prescription for pomalidomide must be accompanied by a Prescription Authorisation Form, which can be completed by completing of the paper Prescription Authorisation Form
- The paper Pharmacy Registration Form and Prescription Authorisation Form are in subsequent sections of this pack.

All patients should be given a Patient Brochure and Patient Pocket Information Card to take home – these materials remind patients of the key educational information and risks of treatment, and can be found in the Information for Patients section of this pack.

For women of childbearing potential, prescriptions of pomalidomide should be limited to a maximum duration of 4 weeks of treatment and continuation of treatment requires a new prescription. Ideally, pregnancy testing, issuing a prescription and dispensing should occur on the same day. Dispensing of pomalidomide should occur within a maximum of 7 days of the prescription and the date of the last negative pregnancy test must be within the 3 days prior to the date of the prescription.

For all other patients, prescriptions of pomalidomide should be limited to a maximum duration of 12 weeks and continuation of treatment requires a new prescription.

1.3 Overview of the Healthcare Professional's Information Pack

All of the IMNOVID Pregnancy Prevention Programme materials are contained within this pack and additional copies can be obtained by using the contact details displayed on the front of this brochure.

You must ensure that your patients fully understand what you have told them about pomalidomide before starting treatment.

This book contains key information for healthcare professionals and contains the following:

- educational information
- therapy management advice to avoid foetal exposure to pomalidomide
- a distribution control system

- Safety advice of relevance to all patients
- Process for follow-up of effectiveness of the measures described in this pack
- Process for reporting adverse events and pregnancy in patients treated with pomalidomide.

This Healthcare Professional's Information Pack also contains Adverse Event Reporting Forms, Treatment Checklists, Algorithms and Treatment Initiation Forms for obtaining consent.

The description of the Pregnancy Prevention Programme and the categorisation of patients based on sex and childbearing potential is set out in the attached Algorithm.

1.4 Teratogenicity: Potential or Actual Foetal Exposure to Pomalidomide

Pomalidomide must never be used by women who are able to become pregnant unless they follow the IMNOVID Pregnancy Prevention Programme described in this pack (Section 2.0).
Since pomalidomide may be present in the semen of male patients, all male and female patients must both follow effective contraceptive measures.

If a female patient or female partner of a male patient misses, or is suspected to have missed her period, or has any abnormality in menstrual bleeding, or suspects she is pregnant, then:

- Pomalidomide must be discontinued immediately
- The woman must have a pregnancy test
- If the pregnancy test is positive, the woman should be referred to a physician experienced in teratology for further evaluation and counselling.

Any positive pregnancy test or suspected foetal exposure to pomalidomide must be reported immediately to the Medicines and Healthcare Products Regulatory Agency (MHRA) and to the Originalis Drug Safety department. In this instance you must:

- Stop treatment immediately, if a female patient
- Refer the patient to a physician specialised or experienced in dealing with teratology for advice and evaluation
- Notify Originalis immediately by contacting the Originalis Drug Safety Department (Email: drugsafetyuk@originalis.eu). Please also complete the Pregnancy Reporting Form included in this pack and send it to the Originalis Drug Safety Department. Originalis will wish to follow-up with you on the progress of all pregnancies

You can report the suspected pregnancy online using the Yellow Card Scheme via www.mhra.gov.uk/yellowcard or by searching for MHRA Yellow Card in the Google Play or Apple App Store. Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary);
- by emailing yellowcard@mhra.gov.uk;
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789;
- or by downloading and printing a form from the Yellow Card section of the MHRA website.

1.5 Safety Advice Relevant to all Patients

In addition to information about the Pregnancy Prevention Programme, this brochure contains important advice for Healthcare Professionals about how to minimise the risk of adverse events during treatment with pomalidomide.

For further information about the appropriate use and safety profile of pomalidomide, please refer to the SmPC which can be found on the emc website: www.medicines.org.uk./emc

2.0 Therapeutic Management Advice to Avoid Foetal Exposure

2.1 Women of Non-Childbearing Potential

Women in the following groups are considered not to have childbearing potential and do not need to undergo pregnancy testing or receive contraceptive advice:

- Age ≥ 50 years and naturally amenorrhoeic for ≥ 1 year. Please note amenorrhoea following cancer therapy or during breastfeeding does not rule out childbearing potential
- Confirmed premature ovarian failure confirmed by a specialist gynaecologist
- Previous bilateral salpingo-oophorectomy, or hysterectomy
- XY genotype, Turner syndrome, uterine agenesis.

Women of childbearing potential are all other women who are menstruating or perimenopausal, even those who abstain from sexual intercourse. Prescribers are advised to refer their patient for a gynaecological opinion if at all unsure as to whether a woman meets the criteria for being of non-childbearing potential.

If a patient does not meet at least one of above criteria, but the prescriber considers the patient to be of non-childbearing potential, then prior approval of any deviation from these stipulated criteria should be sought from the Originalis.

Please contact Originalis Medical Information (Email: MedInfo@originalis.eu).

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2.2 Women of Childbearing Potential

Women of childbearing potential must never take pomalidomide if:

- Pregnant
- They are able to become pregnant, even if not planning to become pregnant, unless all of the conditions of the Pregnancy Prevention Programme are met.

In view of the teratogenic risk of pomalidomide, foetal exposure should be avoided.

Women of childbearing potential must understand the need to avoid pregnancy, and these patients must be adequately informed regarding the use of effective contraceptive measures every time a prescription is issued.

Women of childbearing potential (even if they have amenorrhoea) must use at least one effective method of contraception for at least 4 weeks before therapy, during therapy, and until at least 4 weeks after pomalidomide therapy finished, and even in case of dose interruption. This must be followed unless the patient commits to absolute and continuous abstinence confirmed to her prescriber on a monthly basis.

If your patient is not established on effective contraception, she must be referred to an appropriately trained health care professional for contraceptive advice in order that a contraception can be initiated.

The following can be considered to be examples of suitable methods of contraception:

- Implant
- Levonorgestrel-releasing intrauterine system (IUS)
- Medroxyprogesterone acetate depot
- Tubal sterilisation
- Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses
- Ovulation inhibitory progesterone-only pills (i.e. desogestrel).

Because of the increased risk of venous thromboembolism in patients with multiple myeloma taking pomalidomide and dexamethasone, combined oral contraceptive pills are not recommended. If a patient is currently using combined oral contraception the patient should switch to one of the effective methods listed above. The risk of venous thromboembolism continues for 4 to 6 weeks after discontinuing combined oral contraception. The efficacy of contraceptive steroids may be reduced during co-treatment with dexamethasone.

Implants and levonorgestrel-releasing intrauterine systems are associated with an increased risk of infection at the time of insertion and irregular vaginal bleeding. Prophylactic antibiotics should be considered particularly in patients with neutropenia.

Insertion of copper-releasing intrauterine devices is not recommended due to the potential risks of infection at the time of insertion and menstrual blood loss which may compromise patients with severe neutropenia or severe thrombocytopenia.

Your patient should be advised that if a pregnancy does occur whilst she is receiving pomalidomide, she must stop treatment immediately and immediately inform her physician.

If your patient needs to change or stop her method of contraception during her pomalidomide therapy, she must understand the need to discuss this first with:

- The physician prescribing her method of contraception
- The physician prescribing her pomalidomide.

If a woman of childbearing potential has sexual contact without using an effective contraception method while taking pomalidomide or believes for any reason that she may be pregnant, she must stop treatment and consult her prescriber immediately.

Pregnancy Testing

For women of childbearing potential a pregnancy test must be performed prior to issuing a prescription. This may be embarrassing for some patients and may need to be handled sensitively. A pregnancy test is required even if the patient has not had heterosexual intercourse since her last pregnancy test.

Women of childbearing potential (even if they have amenorrhoea) must have a medically supervised negative pregnancy test prior to issuing a prescription (with a minimum sensitivity of 25 mIU/ml) once she has been established on contraception for at least 4 weeks, at least every 4 weeks during therapy (this includes dose interruptions) and at least 4 weeks after the end of therapy (unless confirmed tubal sterilisation). This includes those women of childbearing potential who confirm absolute and continued abstinence.

Patients who are being prescribed the appropriate contraceptive method by their physician, should inform their physician about pomalidomide treatment. Patients should be advised to inform you if a change or stop of method of contraception is needed.

A pregnancy test must be performed immediately if a patient misses her period, if there is any abnormality in menstrual bleeding, if she has heterosexual intercourse without using a contraceptive method, or if she suspects she is pregnant.

If a female patient has a positive pregnancy test, then:

- Stop treatment immediately
- Refer the patient to a physician specialised or experienced in dealing with teratology for advice and evaluation
- Notify Originalis immediately by contacting Drug Safety Department (Email: drugsafety@originalis.eu). Please also complete the Pregnancy Reporting Form included in this pack and send it to the Originalis Drug Safety Department. Originalis will wish to follow-up with you the outcome of all pregnancies

You can report the suspected pregnancy online using the Yellow Card Scheme via www.mhra.gov.uk/yellowcard or by searching for MHRA Yellow Card in the Google Play or Apple App Store. Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary);
- by emailing yellowcard@mhra.gov.uk;
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789;
- or by downloading and printing a form from the Yellow Card section of the MHRA website.

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2.3 Men

In view of the expected teratogenic risk of pomalidomide, foetal exposure should be avoided. Therefore your male patients must be counselled at treatment initiation on the risks and benefits of pomalidomide therapy including the risk of birth defects, other side effects and important precautions associated with pomalidomide therapy. Inform your patient which are the effective contraceptive methods that his female partner can use.

Pomalidomide is present in human semen. As a precaution, and taking into account special populations with potentially prolonged elimination time such as renal impairment, all male patients taking pomalidomide, including those who have had a vasectomy as seminal fluid may still contain pomalidomide in the absence of spermatozoa, should use condoms throughout treatment duration, during dose interruption and for at least 7 days after cessation of treatment if their partner is pregnant or of childbearing potential and has no contraception. Male patients should not donate semen or sperm during treatment, during dose interruptions and for at least 7 days following discontinuation of pomalidomide.

Patients should be instructed that if their partner does become pregnant whilst he is taking pomalidomide or within 7 days after he has stopped taking pomalidomide, he should inform his prescriber immediately. The partner should inform their physician immediately. It is recommended that she be referred to a physician specialised in teratology for evaluation and advice.

You can report the suspected side effect using the Yellow Card Scheme via www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary);
- by emailing yellowcard@mhra.gov.uk;
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789;
- or by downloading and printing a form from the Yellow Card section of the MHRA website.

2.4 Advice for all Patients

Your patient must be informed not to donate blood during or within 7 days after stopping treatment. If your patient discontinues therapy, they must return any unused pomalidomide to the pharmacy.

Healthcare professionals and caregivers should wear disposable gloves when handling the blister or capsule. Women who are pregnant or suspect they may be pregnant should not handle the blister or capsule.

They must also understand that their pomalidomide is only for them, and it:

- Must not be shared with anyone else, even if they have similar symptoms
- Must be stored away safely so no one else could take the capsules by accident
- Must be kept out of reach and sight of children.

3.0 Healthcare Professional Obligations

Healthcare Professionals have specific obligations that must be followed when prescribing or dispensing pomalidomide, which are:

Prescriber: You must ensure that

- Your patient is fully educated on the risks of pomalidomide
- You complete the appropriate 'Treatment Initiation Form' with your patient before the first prescription is issued
- You provide the patient with a 'Patient Pocket Information Card', Patient Brochure and a copy of the 'Treatment Initiation Form'
- If relevant, your patient is using the appropriate method of contraception
- Female patients of childbearing potential undergo a pregnancy test, which must be negative, before every prescription that you issue
- You complete a 'Prescription Authorisation Form' with every prescription
  - this includes instances where pomalidomide is prescribed to in-patients or if a prescription has to be dispensed in two parts due to the unavailability of sufficient stock to fulfil the prescription
- You prescribe pomalidomide in accordance with the measures described in this brochure and the SmPC, which can be found on the emc website: **www.medicines.org.uk/emc.**

Pharmacist: You must ensure that

- Your pharmacy is registered with the IMNOVID Pregnancy Prevention Programme. Registration will be valid for 2 years Pomalidomide is only dispensed if the prescription is accompanied by a Prescription Authorisation Form. This includes instances where pomalidomide is prescribed to in-patients or if a prescription has to be dispensed in two parts due to the unavailability of sufficient stock to fulfil the prescription
- You check and validate the Prescription Authorisation Form prior to dispensing pomalidomide
- You dispense pomalidomide in accordance with the measures described in this brochure
- You send a copy of the Prescription Authorisation Form immediately to Originalis
- You remind patients of key education messages each time pomalidomide is dispensed.

3.1 Information for Prescribers

3.1.1 Patient and Healthcare Professional Education

As the prescriber, you play a central role in ensuring that pomalidomide is used safely and correctly.

Most importantly, you will be helping to ensure that your patients understand the risks involved in taking pomalidomide and that they are aware of their responsibilities in preventing foetal exposure to the drug. In addition, you may need to help your patients understand the processes involved in the IMNOVID Pregnancy Prevention Programme. This will help to prevent any delays in your patients receiving their treatment.

If you refer your patient to a fertility expert (e.g. obstetrician or gynaecologist) for further contraceptive advice or pregnancy testing counselling, it is your responsibility to ensure that the fertility expert is aware of the IMNOVID Pregnancy Prevention Programme.

3.1.2 Patient Counselling and Education

Because of the different levels of risk, you will need to communicate different information to men, women and children. You must ensure that your patient understands the information before they complete their section of the Treatment Initiation Form.

Please make use of the Patient Brochure and Patient Pocket Information Card to help explain the relevant information. Copies of the Brochure are contained in your 'Healthcare Professional's Information Pack', and your patient should take these materials home to read in their own time or with a relative. Further copies can be obtained by using the contact details displayed on the front of this brochure.

3.1.3 Prescribing Pomalidomide

3.1.3.1 Maximum Prescription Lengths

- For women of childbearing potential, prescriptions of pomalidomide should be limited to a maximum duration of 4 weeks of treatment according to the approved indications dosing regimens (posology; see Introduction) and continuation of treatment requires a new prescription. Dispensing will not occur unless a negative pregnancy test was performed within 3 days prior to the prescription

- For all other patients, prescriptions of pomalidomide should be limited to a maximum duration of 12 weeks and continuation of treatment requires a new prescription.

3.1.3.2 Initial Prescription

Before issuing the initial prescription, you must:

- Counsel the patient on the safe use of pomalidomide in accordance with the measures described in this brochure and the SmPC, which can be found on the emc website: **www.medicines.org.uk/emc**
- Obtain their written confirmation (using the correct Treatment Initiation Form) that they have received and understood this information, and provide the patient with a copy
- Provide the patient with a Patient Brochure and Patient Pocket Information Card
- A paper copy of the 'Prescription Authorisation Form' must be provided to the patient with each pomalidomide prescription, and this will contain:
  - Patient initials, date of birth and diagnosis
  - Prescriber name, signature and date
  - Patient risk category (women of childbearing potential, women of non-childbearing potential, or male)
  - Confirmation that they have received counselling on the safe use of pomalidomide
  - For women of childbearing potential, the pregnancy test date and result.

The patient must present their 'Prescription Authorisation Form' to the pharmacy along with their prescription, and the pharmacy will check this form prior to dispensing pomalidomide.

Once the Prescription Authorisation Form has been checked for completeness, a copy of the Prescription Authorisation Form must be sent to Originalis.

3.1.3.3 Repeat of subsequent prescriptions

The patient must return to the prescriber for every repeat prescription of pomalidomide.

3.2 Information for Pharmacists

As a pharmacist you play an important role in ensuring that pomalidomide is used safely and correctly. Pomalidomide will only be supplied to pharmacies that have completed an 'IMNOVID Pregnancy Prevention Programme, Pharmacy Registration Form' and returned a competed and signed form to Originalis.

3.2.1 Dispensing pomalidomide

It is a requirement of the Pregnancy Prevention Programme that pharmacies wishing to purchase and dispense pomalidomide are registered with Originalis. Registration involves receiving a Healthcare Professional's Information Pack and emailing or posting to Originalis a signed Pharmacy Registration Form to indicate agreement and compliance with the content.

Dispensing of pomalidomide will only be allowed from pharmacies registered with Originalis. Originalis will not authorise purchase and supply of pomalidomide to pharmacies not registered with Originalis.

In order to be registered, the Chief Pharmacist or appointed deputy of the institution wishing to dispense must agree to implement and audit the use of a Prescription Authorisation Form.

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Along with each pomalidomide prescription, prescribers must complete a Prescription Authorisation Form and instruct the patient to provide this to their pharmacy. You must only dispense pomalidomide if the prescriber has annotated this form correctly. When completing the paper Prescription Authorisation Form, it asks the prescriber to confirm:

- The patient's diagnosis
- Whether the patient is male or female
- If female, the patient's childbearing potential
- If of childbearing potential that adequate contraception is in place and the date of the last negative pregnancy test, which must be within the 3 days prior to the date of prescription
- If male, counselling regarding the use of condoms has taken place
- That a Treatment Initiation Form has been completed by the patient
- That the prescriber has read and understood the contents of this Healthcare Professional Information Pack.

When completing the paper Prescription Authorisation Form, it asks the pharmacist to confirm;

- That the Prescription Authorisation Form has been completed in full by the prescriber
- The dispensing for women of childbearing potential is taking place within 7 days of the prescription date
- That the pharmacist has read and understood the contents of this Healthcare Professional Information Pack.

For women of childbearing potential, prescriptions for pomalidomide should be limited to a maximum duration of 4 weeks and continuation of treatment requires a new prescription. Ideally, pregnancy testing, issuing a prescription and dispensing should occur on the same day. Dispensing of pomalidomide should occur within a maximum of 7 days of the prescription and the date of the last negative pregnancy test must be within the 3 days prior to the date of the prescription.

For males and women of non childbearing potential, prescriptions of pomalidomide should be limited to a maximum duration of 12 weeks and continuation of treatment requires a new prescription.

Pharmacies are required to send a copy of every paper Prescription Authorisation Form immediately after dispensing to Originalis (Email: customerservices@originalis.eu).

3.2.2 Dispensing Advice

- Please ensure that you dispense pomalidomide blisters intact; capsules must not be removed from blisters and packaged into bottles
- For each prescription, dispense a maximum of a 4week supply for women of childbearing potential or a 12 week supply for all other patients
- Please educate all pharmacists within your pharmacy about the dispensing procedures for pomalidomide
- Instruct patients to return any unused pomalidomide to the pharmacy. Pharmacies must accept any unused pomalidomide returned by patients for destruction, and follow Good Pharmacy Practice guidelines for destruction of dangerous medicines.

4.0 Follow-up Assessment of the Effectiveness of the Programme

The terms of the IMNOVID Marketing Authorisation require Originalis to assess the effectiveness of the Pregnancy Prevention Programme in order to ensure that all reasonable steps are being taken to reduce the risk of pregnancy exposure in patients treated with pomalidomide.

Originalis is therefore obliged to perform audits at regular intervals and to report appropriately anonymous and aggregated results to the MHRA. Originalis will conduct the audit from all of the completed Prescription Authorisation Forms received.

Pharmacies must send a copy of every completed paper Prescription Authorisation Form to Originalis, then Originalis will be able to conduct the pharmacy audit using these forms and a manual self-audit by pharmacies will not be required. It is critical, therefore, that Prescription Authorisation Forms are completed accurately, and that pharmacies thereby assist Originalis to audit the effectiveness of the Prevention Programme as implemented in the UK.

Originalis is obliged to provide the anonymised reports on the data received from the Prescription Authorisation Forms to the regulatory agencies. The reports are used to assess the effectiveness of risk minimisation activities and Originalis will not be able to comply if pharmacies do not provide ALL their Prescription Authorisation Forms to Originalis.

5.0 Safety Advice Relevant to all Parties

The following section contains advice to Healthcare Professionals about how to minimise the risk of thrombocytopenia and cardiac failure associated with the use of pomalidomide. Please refer also to SmPC (Sections 4.2 Posology and method of administration, 4.3 Contraindications, 4.4 Special warnings and precautions for use and 4.8 Undesirable effects) for complete information on all the risks associated with pomalidomide.

In general, most adverse reactions occurred more frequently during the first 2 to 3 months of treatment. Please note that the posology, adverse event profile and recommendations outlined herein, particularly in respect of neutropenia and thrombocytopenia, relate to the use of pomalidomide within its licensed indication. There is currently insufficient evidence regarding safety and efficacy in any other indication.

When pomalidomide is given in combination with other medicinal products, the corresponding SmPC must be consulted prior to treatment.

5.1 Risk of thrombocytopenia and cardiac failure with pomalidomide

5.1.1 Thrombocytopenia

Thrombocytopenia is one of the major dose-limiting toxicities of treatment with pomalidomide.

It is therefore encouraged to monitor complete blood counts - including platelet count - weekly for the first 8 weeks and monthly thereafter.

A dose modification or interruption may be required. Patients may require use of blood product support and /or growth factors.

Thrombocytopenia can be managed with dose modifications and/or interruptions. Recommended dose modifications during treatment and restart of treatment with pomalidomide are outlined in the table below:

Dose Modification or Interruption Instructions

Toxicity	Dose Modification
Thrombocytopenia • Platelet Count <25 x 10^9/L	Interrupt pomalidomide treatment, follow CBC weekly
• Platelet Count return to ≥50 x 10^9/L	Resume pomalidomide treatment at one dose lower than previous dose
• For each subsequent drop <25 x 10^9/L	Interrupt pomalidomide treatment
• Platelet count return to ≥50 x 10^9/L	Resume pomalidomide treatment at one dose level lower than the previous dose

CBC – Complete Blood Count

To initiate a new cycle of pomalidomide, the the platelet count must be ≥ 50 x 10^9/L.

Thrombocytopenia occurred in 27.0% of patients who received POM + LD-Dex, and 26.8% of patients who received HD-Dex. Thrombocytopenia was Grade 3 or 4 in 20.7% of patients who received POM + LD-Dex and in 24.2% who received HD-Dex. In POM + LD-Dex treated patients, thrombocytopenia was infrequently serious in 1.7% of patients, led to dose reduction in 6.3% of patients, to dose interruption in 8% of patients and to treatment discontinuation in 0.7% of patients (see Section 4.8 of the SmPC).

5.1.2 Cardiac Failure

Cardiac events, including congestive cardiac failure, pulmonary oedema and atrial fibrillation (see Section 4.8 of the SmPC), have been reported, mainly in patients with pre-existing cardiac disease or cardiac risk factors. Appropriate caution should be exercised when considering the treatment of such patients with pomalidomide, including periodic monitoring for signs or symptoms of cardiac events (see Section 4.4 of the SmPC).

5.2 Safety and Off-Label Use

Please note that the posology, adverse event profile and recommendations outlined above, relate to the use of pomalidomide within its licensed indication. Pomalidomide must always be used according to the Pregnancy Prevention Programme described in this pack – these precautions must be followed, irrespective of the treatment setting, including the indication for treatment. It is essential that the patient's diagnosis is entered on the Prescription Authorisation Form - this will allow an assessment of the clinical usage of pomalidomide, which is important for ongoing monitoring of safety.

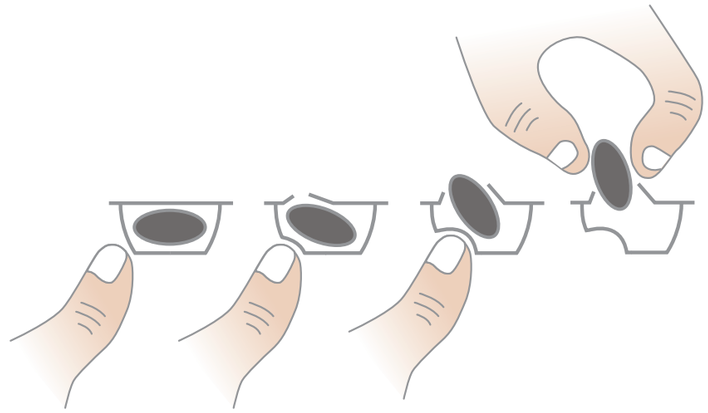
5.3 Points to Consider for Handling the Medicinal Product: For Healthcare Professionals and Caregivers

Keep the blisters with the capsules in the original pack.

Capsules can occasionally become damaged when pressing them out of the blister, especially when the pressure is put onto the middle of the capsule. Capsules should not be pressed out of the blister by putting pressure on the middle nor by putting pressure on both ends as this can result in deformation and breaking of the capsule.

It is recommended to press only on one **side** at the end of the capsule (see figure below) as therefore the pressure is located to one site only which reduces the risk of capsule deformation or breakage.

Healthcare professionals and caregivers should wear disposable gloves when handling the blister or capsule. Gloves should then be removed carefully to prevent skin exposure, placed in a sealable plastic polyethylene bag and disposed of in accordance with local requirements. Hands should then be washed thoroughly with soap and water. Women who are pregnant or suspect they may be pregnant should not handle the blister or capsule. Refer overleaf for further guidance.



When handling the medicinal product use the following precautions to prevent potential exposure if you are a healthcare professional or caregiver

- If you are a woman who is pregnant or suspect that you may be pregnant, you should not handle the blister or capsule
- Wear disposable gloves when handling product and/or packaging (i.e. blister or capsule)
- Use proper technique when removing gloves to prevent potential skin exposure (see overleaf)
- Place gloves in sealable plastic polyethylene bag and dispose according to local requirements.
- Wash hands thoroughly with soap and water after removing gloves
- Patients should be advised never to give pomalidomide to another person.

If a drug product package appears visibly damaged, use the following extra precautions to prevent exposure

- If outer carton is visibly damaged – **Do Not Open**
- If blister strips are damaged or leaking or capsules are noted to be damaged or leaking – **Close Outer Carton Immediately**
- Place the product inside a sealable plastic polyethylene bag
- Return unused pack to the pharmacist for safe disposal as soon as possible.

If product is released or spilled, take proper precautions to minimise exposure by using appropriate personal protection

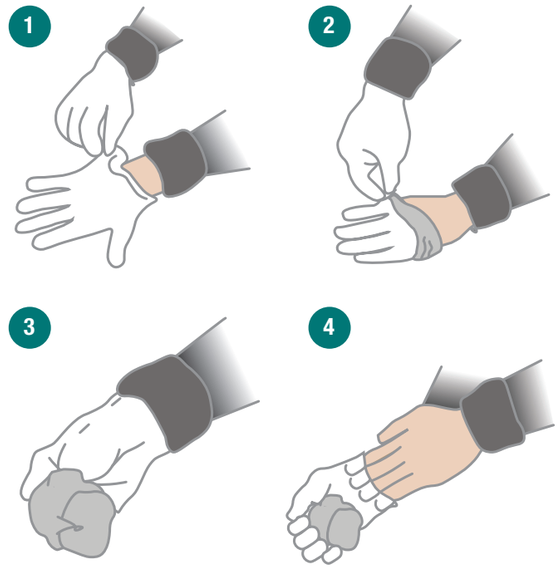
- If capsules are crushed or broken, dust containing drug substance may be released. Avoid dispersing the powder and avoid breathing the powder
- Wear disposable gloves to clean up the powder
- Place a damp cloth or towel over the powder area to minimise entry of powder into the air. Add excess liquid to allow the material to enter solution. After handling, clean the area thoroughly with soap and water and dry it
- Place all contaminated materials including damp cloth or towel and the gloves into a sealable polyethylene plastic bag and dispose in accordance to local requirements for medicinal products
- Wash your hands thoroughly with soap and water after removing the gloves
- Please report to the Originalis Drug Safety Department (Tel: +44 (0)203 630 1244 or drugsafety@originalis.eu).

If the contents of the capsule are attached to the skin or mucous membranes

- If you touch the drug powder, please wash exposed area thoroughly with running water and soap
- If the powder gets in contact with your eye, if worn and if easy to do, remove contact lenses and discard them. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs please contact an ophthalmologist.

Version 2

Proper Technique for Removing Gloves



- Grasp outside edge near wrist (1)
- Peel away from hand, turning glove inside-out (2)
- Hold in opposite gloved hand (3)
- Slide ungloved finger under the wrist of the remaining glove, be careful not to touch the outside of the glove (4)
- Peel off from inside, creating a bag for both gloves
- Discard in appropriate container
- Wash your hands with soap and water thoroughly.

5.4 Blood Donation

All patients should not donate blood during treatment (including dose interruptions) and for at least 7 days after cessation of treatment with pomalidomide.

6.0 Reporting Adverse Events, Suspected and Confirmed Pregnancies, and Foetal Exposures

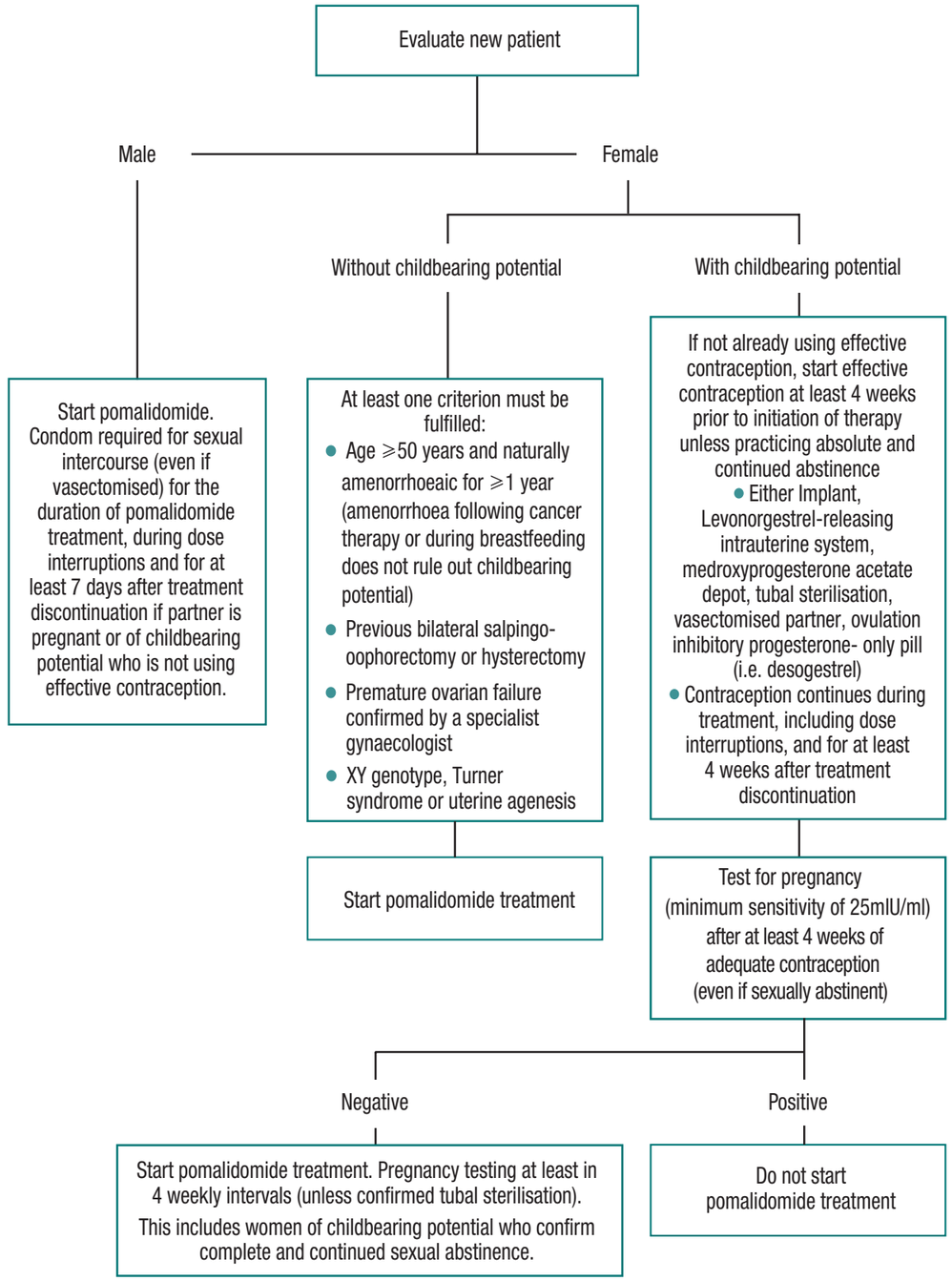
The safe use of pomalidomide is of paramount importance.

Adverse events (and cases of suspected or confirmed pregnancy or foetal exposure) should be reported. Adverse Event Report forms and Pregnancy Reporting forms are included in this pack and should be forwarded to Originalis Medical Information (Tel: +44 (0)203 630 1244 or MedInfo@originalis.eu).

You can report suspected pregnancies and adverse events online using the Yellow Card Scheme via www.mhra.gov.uk/yellowcard or by searching for MHRA Yellow Card in the Google Play or Apple App Store. Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary);
- by emailing yellowcard@mhra.gov.uk;
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789;
- or by downloading and printing a form from the Yellow Card section of the MHRA website.

7.0 Description of the Pregnancy Prevention Programme and Patient Categorisation Algorithm



8.0 Contact Details

Medical Information:

For Information and questions on the Pregnancy prevention Programme, pharmacy registrations and other medical information queries.
Tel: +44 (0)203 630 1244
Email: MedInfo@originalis.eu

Drug Safety:

To report any adverse events to Originalis. Tel: +44 (0)203 630 1244
Email: drugsafety@originalis.eu
Adverse events can also be reported to the MHRA via the Yellow Card scheme website:
www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Customer Services:

For product delivery enquiries. Originalis Customer Services.
Tel: +44 (0)203 630 1688
Email: customerservices@originalis.eu

Originalis

Originalis BV., Diamantweg 4 - 1812RC, Alkmaar – The Netherlands,
Tel.: +44 (0)203 630 1688

Date of preparation of text: May 2022
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Date of preparation of text: May 2022
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IMNOVID® ▼ (pomalidomide) Pharmacy Registration Form – Part 1

To be completed by the Chief Pharmacist or appointed deputy.

Institution name:	
Chief Pharmacist (or appointed deputy):	
Contact telephone number:	
Email:	

Dispensing Address:	Delivery Address (if different):
Tel:	Tel:
Fax:	Fax:
Email:	Email:

Ordering Address (if different to delivery address):

On behalf of . . . . . [institution name], I agree to implement the following risk minimisation procedures when dealing with prescriptions for pomalidomide as specified by Originalis in the IMNOVID Healthcare Professional's Information Pack.

1	I have read and understood the IMNOVID Healthcare Professional's Information Pack.	TICK
2	All pharmacists who dispense pomalidomide will have read and understood the IMNOVID Healthcare Professional's Information Pack.	TICK
3	If supplied with pomalidomide, it will only be used for the purpose of dispensing the product by the Pregnancy Prevention Programme registered pharmacy to the patient.	TICK
4	Prescriptions for pomalidomide will be dispensed only if accompanied by a completed IMNOVID Prescription Authorisation Form.	TICK
5	The pharmacist dispensing pomalidomide will check each prescription and Prescription Authorisation Form for completeness and countersign the authorisation form prior to dispensing.	TICK
6	The information supplied to Originalis on Prescription Authorisation Forms will be used to provide annonymised aggregate reports to the regulatory agencies to assess implementation of the Pregnancy Prevention Programme.	TICK
7	Pomalidomide will be dispensed, checked and stored according to our standard documented procedures for oral anti-cancer medicines.	TICK
8	For woman of childbearing potential, dispensing should occur within a maximum of 7 days of the date of prescription. Dispensing will be limited to no more than a 4-week supply for women of childbearing potential, and 12 weeks for males and women of non-childbearing potential.	TICK
9	After dispensing, IMNOVID Prescription Authorisation Forms will be kept in pharmacy for a minimum of 2 years. A copy of each completed Prescription Authorisation Form will be sent to Originalis.	TICK
10	I will notify Originalis of any change in contact details.	TICK

I understand that registration to obtain and supply pomalidomide will only be granted if I agree to items 1–10 described above as supply of pomalidomide without participation in the required risk minimisation for pregnancy prevention is contrary to the conditions of the marketing authorisation. Registration is valid for 2 years at which point I will confirm that we are continuing to follow the risk minimisation procedures by completing this form and sending to Originalis.

Sign:				
Print:	Date:	DD	MM	YYYY

Email the completed form to CustomerServices@originalis.eu

Originalis BV., Diamantweg 4 - 1812RC, Alkmaar – The Netherlands

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Approved by MHRA:

IMNOVID® ▼ (pomalidomide) Pharmacy Registration Form – Part 2

If you would like to register additional pharmacy sites to be covered by your registration please provide details below.

Institution name:

Additional pharmacy sites covered by registration with Originalis to supply pomalidomide

Name of Hospital/Pharmacy:

Pharmacy purchasing contact:

Dispensing Address:	Delivery Address (if different):
Tel:	Tel:
Fax:	Fax:
Email:	Email:

Ordering Address (if different to delivery address):

Name of Hospital/Pharmacy:

Pharmacy purchasing contact:

Dispensing Address:	Delivery Address (if different):
Tel:	Tel:
Fax:	Fax:
Email:	Email:

Ordering Address (if different to delivery address):

Name of Hospital/Pharmacy:

Pharmacy purchasing contact:

Dispensing Address:	Delivery Address (if different):
Tel:	Tel:
Fax:	Fax:
Email:	Email:

Ordering Address (if different to delivery address):

Email the completed form to CustomerServices@originalis.eu

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Approved by MHRA:

Version 2

IMNOVID®▼ (pomalidomide)
Pregnancy Prevention Programme

Information for Patients Taking Pomalidomide

UK

▼ This medicinal product is subject to additional monitoring.
This will allow quick identification of new safety information.

You can help by reporting any side effects you may get. Report the suspected side effect using the Yellow Card Scheme via www.mhra.gov.uk/yellowcard or by searching for MHRA Yellow Card in the Google Play or Apple App Store. Side effects should also be reported to Originalis Medical Information on +44 (0)203 630 1244 or MedInfo@originalis.eu).

Risk Management Contact Details
Tel: +44 (0)203 630 1244
Email: drugsafety@originalis.eu

Medical Information Quiries
Tel: +44 (0)203 630 1244
Email: MedInfo@originalis.eu

Date of preparation of text: May 2022
RMP/Originalis/Imnovid/UK/002/0522
Approved by MHRA:

This brochure contains information about:

Preventing harm to unborn babies:

If pomalidomide is taken during pregnancy it is expected to cause severe birth defects or death to an unborn baby.

IMNOVID Pregnancy Prevention Programme:

This Programme is designed to make sure that unborn babies are not exposed to pomalidomide. It will provide you with information about what to expect from your treatment, and explain the risks and your responsibilities.

Pomalidomide must never be used by a woman who is pregnant. In addition, it is important to know that pomalidomide passes into men's semen, and is expected to cause severe birth defects or death to an unborn baby. So if you are a male patient, there is a risk if you have unprotected sex with a woman who can become pregnant.

This brochure will help you understand what to do before, during and after taking pomalidomide.

This brochure will not give you information about multiple myeloma, you should ask your prescriber if you have any questions.

Warning: Severe life-threatening birth defects. If pomalidomide is taken during pregnancy it can cause severe birth defects or death to an unborn baby.

Pomalidomide must never be used by women who are pregnant, as just one capsule can cause severe birth defects.

Pomalidomide must never be used by women who are able to become pregnant unless they follow the IMNOVID Pregnancy Prevention Programme.

For complete information on all possible side effects please read the Package Leaflet that comes with your pomalidomide capsules.

This brochure also contains important information about the requirement to avoid blood donation during treatment, the safe handling of pomalidomide and the safe disposal of unused pomalidomide capsules.

For your own health and safety, please read the patient information leaflet and this brochure carefully. If you do not understand something, please ask your prescriber for further explanation.

Contents

Introduction

IMNOVID is the trade name for pomalidomide and it is used to treat adults with a type of cancer called 'multiple myeloma'. Pomalidomide works in a number of different ways:

- by stopping the cancer cells developing
- by stimulating the immune system to attack the cancer cells
- by stopping the formation of blood vessels supplying the cancer cells.

Pomalidomide is either used with:

- two other medicines - called 'bortezomib' (a type of chemotherapy medicine) and 'dexamethasone' (an anti-inflammatory medicine) in people who have had at least one other treatment - including lenalidomide.

Or

- one other medicine - called 'dexamethasone' in people whose myeloma has become worse, despite having at least two other treatments - including lenalidomide and bortezomib.

Pomalidomide is structurally related to thalidomide, which is known to cause severe, life-threatening birth defects, therefore pomalidomide is expected to be harmful to the unborn child.

Pomalidomide has been shown to produce birth defects in animals and it is expected to have a similar effect in humans. Therefore precautions must be taken to avoid exposure to pomalidomide in an unborn baby.

This brochure is part of the "IMNOVID Pregnancy Prevention Programme", which is necessary because if pomalidomide is taken during pregnancy it can cause severe birth defects or death to an unborn baby.

This brochure contains important information about the IMNOVID Pregnancy Prevention Programme. You must read the information carefully and before starting treatment you should:

- Understand the risks of pomalidomide treatment
- Understand the guidelines for taking pomalidomide safely, including how to prevent pregnancy
- Understand what to expect during your initial and follow-up consultations with your prescriber
- Your prescriber will explain to you the risks of pomalidomide treatment and specific instructions that you must follow
- Please make sure that you understand what your prescriber has told you before starting pomalidomide.

If you don't understand something, please ask your prescriber for further explanation.

Pomalidomide and Birth Defects

All medicines can cause unwanted effects or 'side effects'. An extremely important side effect of pomalidomide is that if taken during pregnancy, it can cause severe birth defects or death to an unborn baby. The birth defects include shortened arms or legs, malformed hands or feet, eye or ear defects, and internal organ problems. This means pomalidomide must never be taken by:

- Women who are pregnant
- Women who could become pregnant, unless they follow the IMNOVID Pregnancy Prevention Programme.

Pomalidomide and Other Possible Side Effects

Like all medicines, pomalidomide can cause side effects, although not everybody gets them. Some side effects are more common than others and some are more serious than others. Ask your prescriber or pharmacist if you would like more information, and refer to the Package Leaflet. Most side effects are temporary and can be easily prevented or treated. The most important thing is to be aware of what to expect and what to report to your prescriber. It is important that you talk to your prescriber if you have any side effects during pomalidomide treatment.

You can report suspected pregnancies and side effects online using the Yellow Card Scheme via www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary);
- by emailing yellowcard@mhra.gov.uk;
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789;
- or by downloading and printing a form from the Yellow Card section of the MHRA website.

Before and during the treatment with pomalidomide you will have regular blood tests. This is because your medicine may cause a fall in the number of blood cells that help fight infection (white cells) and in the number of cells that help to stop bleeding (platelets).

Your prescriber should ask you to have a blood test:

- before treatment
- every week for the first 8 weeks of treatment
- at least every month after that for as long as you are taking pomalidomide.

As a result of these tests, your prescriber may change your dose of pomalidomide or stop your treatment. The prescriber may also change the dose or stop the medicine because of your general health.

Pregnancy Prevention Programme

- You should tell your prescriber if you are pregnant or think you may be pregnant or are planning to become pregnant, **as pomalidomide is expected to be harmful to an unborn child.**

If pomalidomide is taken during pregnancy, severe, life-threatening birth defects are expected. If you are pregnant, if you think you may be pregnant or if you are planning to become pregnant you should tell your prescriber and MUST NOT take pomalidomide. Even if you are not having regular periods or are approaching the menopause you may still be able to become pregnant.

What should you tell your prescriber before taking pomalidomide

- If you are pregnant, if you think you may be pregnant or if you are planning to become pregnant, **as pomalidomide is expected to be harmful to an unborn child**
- If you think you are able to become pregnant and need advice on effective contraception
- If you are breastfeeding
- If you have previously had an allergic (hypersensitive) reaction such as rash, itching, swelling, feeling dizzy or trouble breathing while taking related medicines called 'thalidomide' or 'lenalidomide'
- If you have previously had an allergic (hypersensitive) reaction such as rash, itching, swelling, feeling dizzy or trouble breathing to any other ingredient in pomalidomide capsules. Ask your pharmacist for advice
- If you have had a heart attack, have heart failure, have difficulty breathing, if you smoke, have high blood pressure or high cholesterol levels
- If you have a history of thrombosis (blood clots)
- If you are taking or have recently taken any other medicines, including medicines bought without a prescription
- If you have a high total amount of tumour throughout the body, including your bone marrow. This could lead to a condition where the tumours break down and cause unusual levels of chemicals in the blood which can lead to kidney failure. You may also experience an uneven heartbeat. This condition is called tumour lysis syndrome
- If you have or have had neuropathy (nerve damage causing tingling or pain in your hands or feet)
- If you have or have ever had hepatitis B infection. Treatment with pomalidomide may cause the hepatitis B virus to become active again in patients who carry the virus, resulting in a recurrence of the infection. Your prescriber should check whether you have ever had hepatitis B infection
- If you experience or have experienced in the past a combination of any of the following symptoms: rash on face or extended rash, red skin, high fever, flu-like symptoms, enlarged lymph nodes, signs of severe skin reaction called Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) or drug hypersensitivity syndrome, Toxic Epidermal Necrolysis (TEN) or Stevens-Johnson Syndrome (SJS).

Childbearing Potential Assessment

Female patients will be assessed by their prescriber for childbearing potential, and unless you fall into one of the following categories you must follow the contraceptive advice presented in this section:

- You are at least 50 years old and it has been at least one year since your last period (if your periods have stopped because of cancer therapy or during breastfeeding, then there is still a chance you could become pregnant)
- Your womb has been removed (hysterectomy)
- Your fallopian tubes and both ovaries have been removed (bi-lateral salpingo oophorectomy)
- You have premature ovarian failure, confirmed by a specialist gynaecologist
- You have the XY genotype, Turner syndrome or uterine agenesis

You may need an appointment and tests with a specialist in female medicine to confirm that you cannot become pregnant. Every woman who is able to become pregnant even if they are not planning to, must follow the precautions detailed in this section.

Contraception Methods for Women of Childbearing Potential

You must never take pomalidomide if:

- You are pregnant
- You are a woman who is able to become pregnant, even if you are not planning to become pregnant, unless all of the conditions of the Pregnancy Prevention Programme are met.

Pomalidomide is expected to be harmful to the unborn child

- If you are able to become pregnant, you must follow all the necessary measures to prevent you becoming pregnant and ensuring you are not pregnant during treatment. Before starting the treatment, you should ask your prescriber if you are able to become pregnant, even if you think this is unlikely
- If you are able to become pregnant and even if you agree and confirm every month that you will not engage in heterosexual activity, you will have pregnancy tests under the supervision of your prescriber before treatment. These will be repeated at least every 4 weeks during treatment, during dose interruption and at least 4 weeks after the treatment has finished (unless it is confirmed that you have had a tubal sterilisation)
- You should start your pomalidomide treatment as soon as possible after having a negative pregnancy test result and having received pomalidomide
- Unless you commit to absolute and continuous abstinence confirmed on a monthly basis, if you are able to become pregnant you must use at least one effective method of contraception for at least 4 weeks before starting treatment, throughout the duration of your treatment (including dose interruptions), and for at least 4 weeks after stopping treatment. Your prescriber will advise you on appropriate methods of contraception as some types of contraception are not recommended with pomalidomide. It is essential therefore that you discuss this with your prescriber
- If you suspect you are pregnant at any time whilst taking pomalidomide or in the 4 weeks after stopping treatment, you must stop pomalidomide immediately and immediately inform your prescriber. Your prescriber will refer you to a physician specialised or experienced in teratology for evaluation and advice
- Inform the prescriber of your contraception that you are on pomalidomide
- Inform your prescriber of pomalidomide if you have changed or stopped the method of contraception
- Before starting pomalidomide treatment you should discuss with your prescriber whether or not there is any possibility that you could become pregnant. Some women who are not having regular periods or who are approaching the menopause may still be able to become pregnant
- In order to ensure that an unborn baby is not exposed to pomalidomide, your prescriber will complete a Treatment Initiation Form documenting that you have been informed of the requirement for you NOT to become pregnant throughout the duration of your treatment with pomalidomide and for at least 4 weeks after stopping pomalidomide.

Contraception to Prevent Pregnancy

If you are a woman who could become pregnant you must either:

- Use adequate contraception starting at least 4 weeks before pomalidomide treatment, during pomalidomide treatment, during any breaks in pomalidomide treatment and for at least 4 weeks after stopping pomalidomide treatment

  or

- Agree you will not engage in sexual activity with a male partner starting at least 4 weeks before pomalidomide treatment, during pomalidomide treatment, during any breaks in pomalidomide treatment and for at least 4 weeks after stopping pomalidomide treatment. You will be asked to confirm this every month.

Not all types of contraception are suitable during pomalidomide treatment. You and your partner should discuss with your prescriber suitable forms of contraception that you both find acceptable. If necessary, your health care professional can refer you to a specialist for advice on contraception.

Contraception Methods for Males

Pomalidomide is expected to be harmful to the unborn child

- In order to ensure that an unborn baby is not exposed to pomalidomide, your prescriber will complete a Treatment Initiation Form documenting that you have been informed of the requirement for your female partner NOT to become pregnant throughout the duration of your treatment with pomalidomide and for at least 7 days after you stop pomalidomide
- Ask your prescriber to inform you on which are the effective contraceptive methods that your female partner can use
- Pomalidomide passes into human semen. If your partner is pregnant or able to become pregnant, and she doesn't use effective contraception, you must use condoms throughout the duration of your treatment, during dose interruptions and at least 7 days after you stop pomalidomide even if you have had a vasectomy
- If your partner does become pregnant whilst you are taking or within 7 days after you have stopped taking pomalidomide, you should inform your prescriber immediately and your partner should also consult her prescriber immediately
- You should not donate semen or sperm during treatment, during dose interruptions and for at least 7 days after stopping treatment.

Women of Non-childbearing Potential

Pomalidomide is expected to be harmful to the unborn child

- In order to ensure that an unborn baby is not exposed to pomalidomide, your prescriber will complete a Treatment Initiation Form documenting that you are not able to become pregnant.

Pomalidomide Treatment

Before Starting Your Treatment

Your prescriber will talk to you about what to expect from your treatment, and explain the risks and your responsibilities. If there is anything you do not understand, please ask your prescriber to explain it further.

Before starting treatment your prescriber will ask you to read and sign a Treatment Initiation Form, which confirms that while taking pomalidomide:

- You understand the risks of birth defects
- You agree not to become pregnant
- You understand the other important safety messages. Your prescriber will keep this form with your medical records and will also provide you with a copy.

Safety Information for all Patients

- You must never take pomalidomide if you are allergic to pomalidomide or to any of the other ingredients contained in the capsule
- You should never share pomalidomide with anyone else
- You should always return any unused capsules to the pharmacist for safe disposal as soon as possible
- You should not donate blood during treatment, during dose interruptions, or for at least 7 days after stopping treatment
- If you experience any side effects whilst taking pomalidomide you should tell your prescriber or pharmacist
- For additional information, please refer to the Package Leaflet.

Receiving Your Prescription

Your prescriber will provide you with a 'Prescription Authorisation Form' that must be provided to the pharmacist, which confirms that all of the Imnovid Pregnancy Prevention Programme measures have been followed. Your pharmacist will ask to review this documentation prior to dispensing your pomalidomide.

For women of childbearing potential your prescriber will write a prescription for no more than 4 weeks supply and you must have the medication dispensed within 7 days of the prescription date.

For women of non-childbearing potential and male patients your prescriber will write a prescription for no more than 12 weeks supply.

You will need to see your prescriber each time you need a repeat prescription.

How To Take Your Medication

Your pharmacist can give you help and advice on taking your medicines. Some people find it helpful to mark on a calendar when they have taken their medicines each day or to set an alarm clock to remind them to take their medicines.

- Your prescriber will prescribe a dose of pomalidomide suited to you
- Your prescriber may adjust your dose depending on the result of blood tests and any side-effects you may experience
- Do not take more capsules than your prescriber has prescribed. If in doubt, ask your prescriber or pharmacist for advice
- Pomalidomide capsules should be swallowed whole, with a glass of water, and can be taken with or without food
- Pomalidomide can be taken at any time of day but it should be taken at approximately the same time each day.

What to do if you have taken more than the prescribed dose of pomalidomide

If you accidentally take too many capsules, contact your prescriber immediately.

Taking other medicines

Please tell your prescriber or pharmacist if you are taking or have recently taken any other medicines, including medicines bought without a prescription. If you are seeing a different prescriber or other healthcare professional for treatment (your dentist for example) you should tell them that you are taking pomalidomide and dexamethasone.

How to store pomalidomide safely

- Keep your pomalidomide in a safe place out of the reach and sight of children
- Keep your pomalidomide capsules in the original box at room temperature
- Do not use after the expiry date written on the box.

End of Treatment Requirements for All Patients

After completing your pomalidomide treatment, it is important that:

- You return any unused pomalidomide capsules to your pharmacist
- You do not donate blood for at least 7 days.

Additional advice for women of childbearing potential:

- Continue using your effective method of contraception for at least a further 4 weeks
- Your prescriber will perform a final pregnancy test after at at least 4 weeks, unless it is confirmed you have had a tubal sterilisation.

Additional advice for male patients:

- If you have been using an effective method of contraception, you must continue doing so for at least a further 7 days
- If your female partner has been using an effective method of contraception, she must continue doing so for at least a further 4 weeks
- Do not donate semen or sperm for at least 7 days.

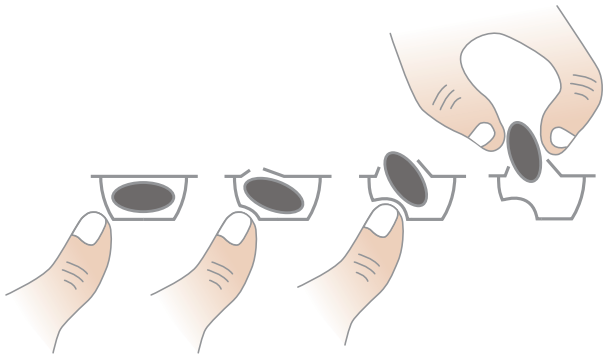
Points to Consider for Handling the Medicinal Product: For Patients, Family Members and Caregivers

Keep the blisters with the capsules in the original pack.

Capsules can occasionally become damaged when pressing them out of the blister, especially when the pressure is put onto the middle of the capsule. Capsules should not be pressed out of the blister by putting pressure on the middle nor by putting pressure on both ends as this can result in deformation and breaking of the capsule.

It is recommended to press only on one site at the end of the capsule (see figure below) as therefore the pressure is located to one site only which reduces the risk of capsule deformation or breakage.

Healthcare professionals and caregivers should wear disposable gloves when handling the blister or capsule. Gloves should then be removed carefully to prevent skin exposure, placed in a sealable plastic polyethylene bag and disposed of in accordance with local requirements. Hands should then be washed thoroughly with soap and water. Women who are pregnant or suspect they may be pregnant should not handle the blister or capsule. Refer overleaf for further guidance.



When handling the medicinal product use the following precautions to prevent potential exposure if you are a family member and/or caregiver

- If you are a woman who is pregnant or suspect that you may be pregnant, you should not handle the blister or capsule
- Wear disposable gloves when handling product and or packaging (i.e., blister or capsule)
- Use proper technique when removing gloves to prevent potential skin exposure (see below)
- Place gloves in sealable plastic polyethylene bag and dispose according to local requirements
- Wash hands thoroughly with soap and water after removing gloves
- Patients should be advised never to give pomalidomide to another person.

If a drug product package appears visibly damaged, use the following extra precautions to prevent exposure

- If outer carton is visibly damaged – **Do Not Open**
- If blister strips are damaged or leaking or capsules are noted to be damaged or leaking – **Close Outer Carton Immediately**
- Place the product inside a sealable plastic polyethylene bag
- Return unused pack to the pharmacist for safe disposal as soon as possible.

If product is released or spilled, take proper precautions to minimise exposure by using appropriate personal protection

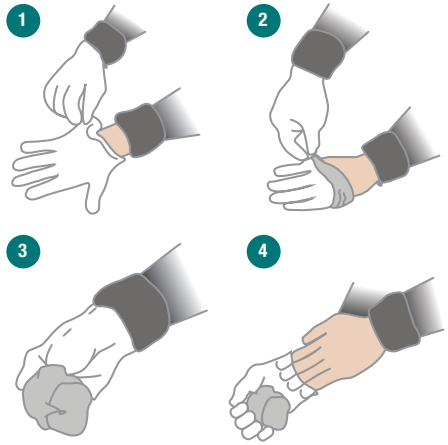
- If capsules are crushed or broken, dust containing drug substance may be released. Avoid dispersing the powder and avoid breathing the powder
- Wear disposable gloves to clean up the powder
- Place a damp cloth or towel over the powder area to minimise entry of powder into the air. Add excess liquid to allow the material to enter solution. After handling, clean the area thoroughly with soap and water and dry it
- Place all contaminated materials including damp cloth or towel and the gloves into a sealable polyethylene plastic bag and dispose in accordance to local requirements for medicinal products
- Wash your hands thoroughly with soap and water after removing the gloves
- Please report to the prescriber and/or pharmacist immediately.

If the contents of the capsule are attached to the skin or mucous membranes

- If you touch the drug powder, please wash exposed area thoroughly with running water and soap
- If the powder gets in contact with your eye, if worn and if easy to do, remove contact lenses and discard them. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs please contact an ophthalmologist.

Proper Technique for Removing Gloves

- Grasp outside edge near wrist (1)
- Peel away from hand, turning glove inside-out (2)
- Hold in opposite gloved hand (3)
- Slide ungloved finger under the wrist of the remaining glove, be careful not to touch the outside of the glove (4)
- Peel off from inside, creating a bag for both gloves
- Discard in appropriate container
- Wash your hands with soap and water thoroughly.



Personal Notes

Please use this space to write down any questions for your prescriber for discussion at your next appointment.

Check List

Please use this check list to confirm that you have understood all of the important information regarding your pomalidomide treatment.

All Patients

- ☐ Yes, I have received and understood all the information on the risks of birth defects associated with taking pomalidomide.
- ☐ Yes, I have received and understood all the information on the risks of other side effects associated with taking pomalidomide.
- ☐ Yes, I have understood that I must not donate blood during treatment (including dose interruptions), and for at least 7 days after stopping treatment.
- ☐ Yes, I understand that I need to sign the Treatment Initiation Form before starting treatment.

Male Patients

- ☐ Yes, I have understood the need to use condoms during treatment, during dose interruption and for at least 7 days after stopping pomalidomide, if I have a female partner who is pregnant or is able to get pregnant and not using effective contraception.
- ☐ Yes, I have understood I must not donate semen or sperm during treatment (including during dose interruptions) and for at least 7 days after stopping pomalidomide.

Female Patients who can become pregnant

- ☐ Yes, I will use one effective method of contraception for at least 4 weeks before starting pomalidomide, during therapy (even in the case of dose interruptions) and for at least 4 weeks after I have stopped pomalidomide treatment.
- ☐ Yes, I understand that I need to have a negative pregnancy test result before starting to take my treatment, and for at least every 4 weeks during treatment and at least 4 weeks after stopping treatment (except in the case of confirmed tubal sterilisation).

Remember, your pharmacist can give you help and advice on taking your medicines.

Emergency contact information:

Emergency Prescriber Contact:

Telephone number during office hours:

Telephone number after office hours:

For complete information on the side effects of pomalidomide, patients should read the Package Leaflet and HCPs should read the Summary of Product Characteristics.

Date of preparation of text: May 2022
RMP/Originalis/Imnovid/UK/002/0522

Approved by MHRA:

Version 2

IMNOVID®▼ (pomalidomide)

This patient is on pomalidomide.

Information for patients:

- You MUST tell your prescriber immediately if you experience any symptom that causes concern
- You MUST inform your prescriber immediately if you suspect that you or your female partner is pregnant.

Date of preparation of text: May 2022
RMP/Originalis/Imnovid/UK/002/0522

Approved by MHRA:

Prescription Details:

Prescription date:	*DD*	*MM*	*YYYY*
Has the patient received counselling?:	Yes / No		
Childbearing potential assessment:	WCBP / WNCBP / Male		

This patient is receiving pomalidomide for treatment of:

- ☐ Multiple Myeloma or
- ☐ Relapsed and Refractory Multiple Myeloma

Version 2

Information for patients and healthcare professionals:

Pomalidomide is an immunomodulator and is an expected human teratogen therefore;

- Female patients of childbearing potential must use at least one effective method of contraception and male patients with pregnant partners or partners of childbearing potential not using effective contraception must use condoms (even if man has had a vasectomy)
- Female patients of childbearing potential must have regular pregnancy tests to ensure that they are not pregnant, except in the case of confirmed tubal sterilisation.

Date of preparation of text: May 2022
RMP/Originalis/Imnovid/UK/002/0522

CONTENTS

Date of preparation of text: May 2022
RMP/Originalis/Imnovid/UK/002/0522

IMNOVID®▼ (pomalidomide) Pregnancy Prevention Programme

Male Treatment Initiation Form

UK

Date of preparation of text: May 2022
RMP/Originalis/Imnovid/UK/002/0522
Approved by MHRA:

Introduction

This Treatment Initiation Form must be completed for each male patient prior to the initiation of their pomalidomide treatment. The form should be retained with their medical records, and a copy provided to the patient.

It is mandatory that males receive counselling and education to be made aware of the risks of pomalidomide.

The aim of the Treatment Initiation Form is to protect patients and any possible foetuses by ensuring that patients are fully informed of and understand the risk of teratogenicity and other adverse effects associated with the use of pomalidomide. It is not a contract and does not absolve anybody from his/her responsibilities with regard to the safe use of the product and prevention of foetal exposure.

Warning: Pomalidomide must not be taken during pregnancy, since a teratogenic effect in humans is expected. Pomalidomide is structurally related to thalidomide. Thalidomide is a known human teratogen that causes severe life threatening birth defects. Pomalidomide was found to be teratogenic in both rats and rabbits when administered during the period of major organogenesis. The conditions of the Pregnancy Prevention Programme must be fulfilled for all patients unless there is reliable evidence that the patient does not have childbearing potential.

If pomalidomide is taken during pregnancy, it is expected to cause severe birth defects or death to an unborn baby.

Patient Details

Patient First Name:																						
Patient Last Name:																						

Date of Birth:	*DD*	*MM*	*YYYY*	Counselling Date:	*DD*	*MM*	*YYYY*

Pregnancy Prevention

The patient confirms that:	
They will use a condom during sexual intercourse with a woman of childbearing potential	*Tick*
Their female partner is using an effective method of contraception	*Tick*
Their female partner is of non-childbearing potential	*Tick*
They are committed to complete and absolute abstinence	*Tick*

Prescriber Confirmation

I have fully explained to the patient named above the nature, purpose and risks of the treatment associated with **pomalidomide**, especially the risks to women of childbearing potential.
I will comply with all my obligations and responsibilities as the prescriber of pomalidomide.

Prescriber First Name :	
Prescriber Last Name:	

Prescriber Signature:		Date:	DD	MM	YYYY

Patient: please read thoroughly and initial the adjacent box if you agree with the statement

I understand that pomalidomide is structurally related to thalidomide, which is known to cause severe life-threatening birth defects, therefore pomalidomide is expected to be harmful to the unborn child.	*Patient initials*
I understand that severe birth defects may occur with the use of pomalidomide. I have been warned by my prescriber that any unborn baby has a high risk of birth defects may and could even die if a woman is pregnant or becomes pregnant while taking pomalidomide.	*Patient initials*
I understand that pomalidomide passes into human semen. If my partner is pregnant or able to become pregnant, and she doesn't use effective contraception, I must use condoms throughout the duration of my treatment, during dose interruptions and for at least 7 days after I stop pomalidomide even if I have had a vasectomy.	*Patient initials*
I know that I must inform my prescriber immediately if I think that my partner may be pregnant whilst I am taking pomalidomide or within 7 days after I have stopped taking pomalidomide and my partner should be referred to a physician specialised or experienced in teratology for evaluation and advice.	*Patient initials*
I understand that pomalidomide will be prescribed ONLY for me. I must not share it with ANYONE.	*Patient initials*
I have read the pomalidomide Patient Brochure and understand the contents, including the information about other possible important health problems (side effects) associated with the use of pomalidomide.	*Patient initials*
I know that I cannot donate blood while taking pomalidomide (including dose interruptions) or for at least 7 days after stopping treatment.	*Patient initials*
I know that I cannot donate semen or sperm while taking pomalidomide, during dose interruptions and for at least 7 days after discontinuation of pomalidomide.	*Patient initials*
I understand that I must return any unused pomalidomide capsules to my pharmacy at the end of my treatment.	*Patient initials*
I have been informed about which are effective contraceptive methods that my female partner can use.	*Patient initials*
I have been informed about the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with pomalidomide.	*Patient initials*

Patient Confirmation

I confirm that I understand and will comply with the requirements of the IMNOVID® Pregnancy Prevention Programme, and I agree that my prescriber can initiate my treatment with pomalidomide.

This form will be kept by your doctor. Your personal data (collected on the prescription authorisation form or "PAF") will be processed by Originalis, as the marketing authorisation holder of Imnovid for the purpose(s) of managing the Pregnancy Prevention Programme.

Your data will be kept for as long as necessary, for the purposes of compliance with the Risk Management Plan legal obligations and for storage purposes.

Should you have any queries in relation to the use of your personal data please contact your doctor or Originalis at: customerservices@originalis.eu. If you are unhappy about how your personal data is being processed, you have the right to lodge a complaint with the supervisory authority.

Patient Signature:		Date:	*DD*	*MM*	*YYYY*

Statement of the interpreter (where appropriate)

I have interpreted the information above to the patient/parent to the best of my ability and in a way in which I believe she/he/they can understand. She/he/they agree to follow the necessary precautions to prevent an unborn child being exposed to pomalidomide.

Interpreter Signature:		Date:	*DD*	*MM*	*YYYY*

Originalis

Originalis BV., Diamantweg 4 - 1812RC, Alkmaar – The Netherlands
Tel.: +44 (0)203 630 1688

Date of preparation of text: May 2022
RMP/Originalis/Imnovid/UK/002/0522
Approved by MHRA:

IMNOVID®▼ (pomalidomide) Pregnancy Prevention Programme

Woman of Childbearing Potential Treatment Initiation Form

UK

Date of preparation of text: May 2022
RMP/Originalis/Imnovid/UK/002/0522
Approved by MHRA:

Introduction

This Treatment Initiation Form must be completed for each woman of childbearing potential prior to the initiation of their pomalidomide treatment. The form should be retained with their medical records, and a copy provided to the patient.

It is mandatory that women of childbearing potential receive counselling and education to be made aware of the risks of pomalidomide. Pomalidomide is contraindicated in women of childbearing potential unless all terms of counselling are met.

The aim of the Treatment Initiation Form is to protect patients and any possible foetuses by ensuring that patients are fully informed of and understand the risk of teratogenicity and other adverse effects associated with the use of pomalidomide. It is not a contract and does not absolve anybody from his/her responsibilities with regard to the safe use of the product and prevention of foetal exposure.

Warning: Pomalidomide must not be taken during pregnancy, since a teratogenic effect in humans is expected. Pomalidomide is structurally related to thalidomide. Thalidomide is a known human teratogen that causes severe life threatening birth defects. Pomalidomide was found to be teratogenic in both rats and rabbits when administered during the period of major organogenesis. The conditions of the Pregnancy Prevention Programme must be fulfilled for all patients unless there is reliable evidence that the patient does not have childbearing potential.

If pomalidomide is taken during pregnancy, it is expected to cause severe birth defects or death to an unborn baby.

Patient Details

Patient First Name:																							
Patient Last Name:																							

Date of Birth:	DD	MM	YYYY	Counselling Date:	DD	MM	YYYY

Contraceptive Referral

Contraceptive referral required		YES	NO
Contraceptive referral made	DD	MM	YYYY
Contraceptive consultation conducted on	DD	MM	YYYY

Pregnancy Prevention

The patient has been established on one of the following for at least 4 weeks	
Implant	Tick
Levonorgestrel-releasing intrauterine system (IUS)	Tick
Medroxyprogesterone acetate depot	Tick
Tubal sterilization	Tick
Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses	Tick
Ovulation inhibitory progesterone-only pills (i.e. desogestrel)	Tick
Committed to complete and absolute abstinence	Tick

Pregnancy Test

Date of last negative pregnancy test	DD	MM	YYYY

Pomalidomide treatment cannot start until the patient has been established on effective method of contraception for at least 4 weeks, or commits to complete and continuous abstinence, and obtains a negative pregnancy test.

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RMP/Originalis/Imnovid/UK/002/0522

Prescriber Confirmation

I have fully explained to the patient named above the nature, purpose and risks of the treatment associated with pomalidomide, especially the risks to women of childbearing potential.
I will comply with all my obligations and responsibilities as the prescriber of pomalidomide.

Prescriber First Name :			
Prescriber Last Name:			
Prescriber Signature:		Date:	DD MM YYYY

Patient: please read thoroughly and initial the adjacent box if you agree with the statement

I understand that pomalidomide is structurally related to thalidomide, which is known to cause severe life-threatening birth defects, therefore pomalidomide is expected to be harmful to the unborn child.	Patient initials
I understand that severe birth defects may occur with the use of pomalidomide. I have been warned by my prescriber that any unborn baby has a high risk of birth defects and could even die if a woman is pregnant or becomes pregnant while taking pomalidomide.	Patient initials
I understand that I must not take pomalidomide if I am pregnant or plan to become pregnant.	Patient initials
I understand that I must use at least one effective method of contraception without interruption, for at least 4 weeks before starting treatment, throughout the entire duration of treatment and even in case of dose interruptions, and for at least 4 weeks after the end of treatment, or commit to absolute and continuous sexual abstinence confirmed on a monthly basis. An effective method of contraception must be initiated by an appropriately trained healthcare professional.	Patient initials
I understand that if I need to change or stop my method of contraception I will discuss this first with the physician prescribing my contraception and the physician prescribing my pomalidomide.	Patient initials
I understand that before starting pomalidomide treatment I must have a medically supervised pregnancy test. Unless it is confirmed I have had a tubal sterilisation, I will then have a pregnancy test every 4 weeks during treatment, and a test at least 4 weeks after the end of treatment.	Patient initials
I understand that I must immediately stop taking pomalidomide and inform my prescriber if I become pregnant while taking this drug; or if I miss my menstrual period or experience any unusual menstrual bleeding; or think FOR ANY REASON that I may be pregnant.	Patient initials
I understand that pomalidomide will be prescribed ONLY for me. I must not share it with ANYONE.	Patient initials
I have read the pomalidomide Patient Brochure and understand the contents, including the information about other possible health problems (side effects) associated with the use of pomalidomide.	Patient initials
I know that I cannot donate blood while taking pomalidomide (including dose interruptions) or for at least 7 days after stopping treatment.	Patient initials
I understand that I must return any unused pomalidomide capsules to my pharmacy at the end of my treatment.	Patient initials
I understand that even if I have amenorrhoea I must comply with advice on contraception.	Patient initials
I have been informed about the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with pomalidomide.	Patient initials

Patient Confirmation

I confirm that I understand and will comply with the requirements of IMNOVID® Pregnancy Prevention Programme, and I agree that my prescriber can initiate my treatment with pomalidomide.

This form will be kept by your doctor. Your personal data (collected on the prescription authorisation form or "PAF") will be processed by Originalis, as the marketing authorisation holder of Imnovid for the purpose(s) of managing the Pregnancy Prevention Programme.

Your data will be kept for as long as necessary, for the purposes of compliance with the Risk Management Plan legal obligations and for storage purposes.

Should you have any queries in relation to the use of your personal data please contact your doctor or Originalis at: customerservices@originalis.eu. If you are unhappy about how your personal data is being processed, you have the right to lodge a complaint with the supervisory authority.

Patient Signature:		Date:	DD	MM	YYYY

Statement of the interpreter (where appropriate)

I have interpreted the information above to the patient/parent to the best of my ability and in a way in which I believe she/he/they can understand. She/he/they agree to follow the necessary precautions to prevent an unborn child being exposed to pomalidomide.

Interpreter Signature:		Date:	DD	MM	YYYY

Originalis

Originalis BV., Diamantweg 4 - 1812RC, Alkmaar – The Netherlands
Tel.: +44 (0)203 630 1688

Date of preparation of text: May 2022
RMP/Originalis/Imnovid/UK/002/0522
Approved by MHRA:

IMNOVID®▼ (pomalidomide) Pregnancy Prevention Programme

Woman of Non-Childbearing Potential Treatment Initiation Form

UK

Date of preparation of text: May 2022
RMP/Originalis/Imnovid/UK/002/0522
Approved by MHRA:

Introduction

This Treatment Initiation Form must be completed for each woman not of childbearing potential prior to the initiation of their pomalidomide treatment. The form should be retained with their medical records, and a copy provided to the patient.

It is mandatory that women of non-childbearing potential receive counselling and education to be made aware of the risks of pomalidomide.

The aim of the Treatment Initiation Form is to protect patients and any possible foetuses by ensuring that patients are fully informed of and understand the risk of teratogenicity and other adverse effects associated with the use of pomalidomide. It is not a contract and does not absolve anybody from his/her responsibilities with regard to the safe use of the product and prevention of foetal exposure.

Warning: Pomalidomide must not be taken during pregnancy, since a teratogenic effect in humans is expected. Pomalidomide is structurally related to thalidomide. Thalidomide is a known human teratogen that causes severe life threatening birth defects. Pomalidomide was found to be teratogenic in both rats and rabbits when administered during the period of major organogenesis. The conditions of the Pregnancy Prevention Programme must be fulfilled for all patients unless there is reliable evidence that the patient does not have childbearing potential.

If pomalidomide is taken during pregnancy, it is expected to cause severe birth defects or death to an unborn baby.

Patient Details

Patient First Name:																							
Patient Last Name:																							

Date of Birth:	*DD*	*MM*	*YYYY*	Counselling Date:	*DD*	*MM*	*YYYY*

Prescriber Confirmation

I have fully explained to the patient named above the nature, purpose and risks of the treatment associated with pomalidomide, especially the risks to women of childbearing potential.
I will comply with all my obligations and responsibilities as the prescriber of pomalidomide.

Prescriber First Name :																					
Prescriber Last Name:																					

Prescriber Signature:		Date:	*DD*	*MM*	*YYYY*

Patient: please read thoroughly and initial the adjacent box if you agree with the statement

I understand that pomalidomide is structurally related to thalidomide, which is known to cause severe life-threatening birth defects, therefore pomalidomide is expected to be harmful to the unborn child.	*Patient initials*
I understand that severe birth defects can occur with the use of pomalidomide. I have been warned by my prescriber that any unborn baby has a high risk of birth defects and could even die if a woman is pregnant or becomes pregnant while taking pomalidomide.	*Patient initials*
I understand that pomalidomide will be prescribed ONLY for me. I must not share it with ANYONE.	*Patient initials*
I have read the pomalidomide Patient Brochure and understand the contents, including the information about other possible health problems (side effects) associated with the use of pomalidomide.	*Patient initials*
I know that I cannot donate blood while taking pomalidomide (including dose interruptions) or for at least 7 days after stopping treatment.	*Patient initials*
I understand that I must return any unused pomalidomide capsules to my pharmacy at the end of my treatment.	*Patient initials*
I have been informed about the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with pomalidomide.	*Patient initials*

Patient Confirmation

I confirm that I understand and will comply with the requirements of IMNOVID® Pregnancy Prevention Programme, and I agree that my prescriber can initiate my treatment with pomalidomide.

This form will be kept by your doctor. Your personal data (collected on the prescription authorisation form or "PAF") will be processed by Originalis, as the marketing authorisation holder of Imnovid for the purpose(s) of managing the Pregnancy Prevention Programme.

Your data will be kept for as long as necessary, for the purposes of compliance with the Risk Management Plan legal obligations and for storage purposes.

Should you have any queries in relation to the use of your personal data please contact your doctor or Originalis at: customerservices@originalis.eu. If you are unhappy about how your personal data is being processed, you have the right to lodge a complaint with the supervisory authority.

Patient Signature:		Date:	DD	MM	YYYY

Statement of the interpreter (where appropriate)

I have interpreted the information above to the patient/parent to the best of my ability and in a way in which I believe she/he/they can understand. She/he/they agree to follow the necessary precautions to prevent an unborn child being exposed to pomalidomide.

Interpreter Signature:		Date:	DD	MM	YYYY

Originalis

Originalis BV., Diamantweg 4 - 1812RC, Alkmaar – The Netherlands
Tel.: +44 (0)203 630 1688

Date of preparation of text: May 2022
RMP/Originalis/Imnovid/UK/002/0522
Approved by MHRA:

CONTENTS

Prescription Authorisation Forms

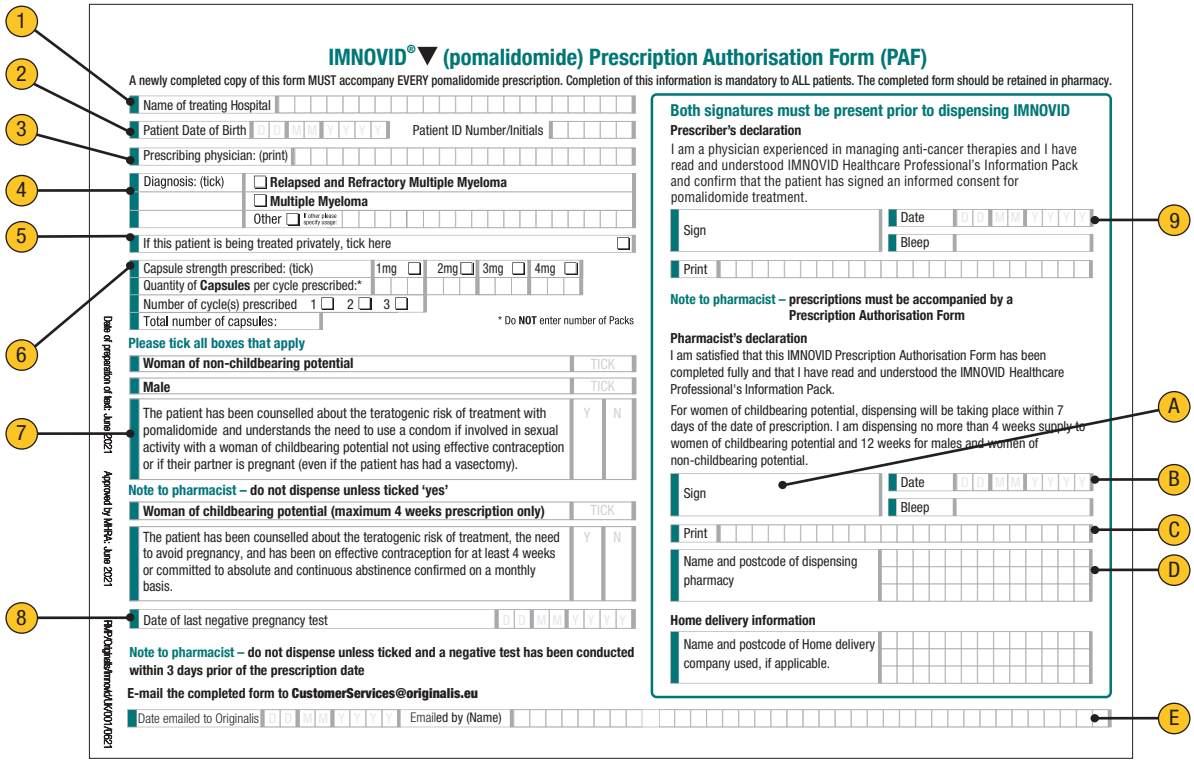
You will need to complete a Prescription Authorisation Form with every prescription for pomalidome (completed forms must be sent to Originalis).

→

Date of preparation of text: May 2022
RMP/Originalis/Imnovid/UK/002/0522

Prescription Authorisation Form (PAF) completion guide - Dual Format

This guide will help you to complete the IMNOVID®▼ (pomalidomide) Prescription Authorisation Form. The form is in the Healthcare Professional's Information Pack and the 'How-to Guide' for Pharmacists, and must be completed each time you prescribe pomalidomide for all patients.



IMNOVID®▼ (pomalidomide) Prescription Authorisation Form (PAF)

A newly completed copy of this form MUST accompany EVERY pomalidomide prescription. Completion of this information is mandatory to ALL patients. The completed form should be retained in pharmacy.

1 Name of treating Hospital

2 Patient Date of Birth D D M M Y Y Y Y Patient ID Number/Initials

3 Prescribing physician: (print)

4 Diagnosis: (tick) ☐ Relapsed and Refractory Multiple Myeloma ☐ Multiple Myeloma Other ☐ If other please specify usage:

5 If this patient is being treated privately, tick here ☐

6 Capsule strength prescribed: (tick) 1mg ☐ 2mg ☐ 3mg ☐ 4mg ☐
Quantity of **Capsules** per cycle prescribed:*
Number of cycle(s) prescribed 1 ☐ 2 ☐ 3 ☐
Total number of capsules:
* Do **NOT** enter number of Packs

Please tick all boxes that apply

Woman of non-childbearing potential TICK
Male TICK

7 The patient has been counselled about the teratogenic risk of treatment with pomalidomide and understands the need to use a condom if involved in sexual activity with a woman of childbearing potential not using effective contraception or if their partner is pregnant (even if the patient has had a vasectomy). Y N

Note to pharmacist – **do not dispense unless ticked 'yes'**

Woman of childbearing potential (maximum 4 weeks prescription only) TICK

The patient has been counselled about the teratogenic risk of treatment, the need to avoid pregnancy, and has been on effective contraception for at least 4 weeks or committed to absolute and continuous abstinence confirmed on a monthly basis. Y N

8 Date of last negative pregnancy test D D M M Y Y Y Y

Note to pharmacist – **do not dispense unless ticked and a negative test has been conducted within 3 days prior of the prescription date**

E-mail the completed form to CustomerServices@originalis.eu

Date emailed to Originalis D D M M Y Y Y Y Emailed by (Name)

Date of preparation of text: June 2021 Approved by MHRA: June 2021 RMP/Originalis/Imnovid/UK/001/0521

Both signatures must be present prior to dispensing IMNOVID

Prescriber's declaration

I am a physician experienced in managing anti-cancer therapies and I have read and understood IMNOVID Healthcare Professional's Information Pack and confirm that the patient has signed an informed consent for pomalidomide treatment.

Sign Date D D M M Y Y Y Y 9
Bleep
Print

Note to pharmacist – **prescriptions must be accompanied by a Prescription Authorisation Form**

Pharmacist's declaration

I am satisfied that this IMNOVID Prescription Authorisation Form has been completed fully and that I have read and understood the IMNOVID Healthcare Professional's Information Pack.

For women of childbearing potential, dispensing will be taking place within 7 days of the date of prescription. I am dispensing no more than 4 weeks supply to women of childbearing potential and 12 weeks for males and women of non-childbearing potential.

A
Sign Date D D M M Y Y Y Y B
Bleep
Print C
Name and postcode of dispensing pharmacy D

Home delivery information

Name and postcode of Home delivery company used, if applicable.

E

Instructions for prescribers

1. Print the full hospital name where the patient is treated.
2. Print the patient's date of birth and initials. If the middle initial is not known please use an underscore (e.g. J_S for John Smith). Do not provide confidential information (e.g. Patient Name and Hospital Number).
3. Print your name clearly.
4. Print the diagnosis – this will allow an assessment of the clinical usage of pomalidomide, which is important for ongoing monitoring of the appropriateness of the Pregnancy Prevention Programme.
5. Please tick this box if the patient is a private patient and not receiving treatment through the NHS.
6. Enter the capsule strength and the patient's treatment cycle number – this should be completed for ALL patients, irrespective of the diagnosis.
7. Complete this section appropriately to indicate that counselling and appropriate contraception has occurred.
   This is a requirement of the Pregnancy Prevention Programme.
8. For women of childbearing potential you must provide a valid negative pregnancy test date (within 3 days prior to prescribing). If this is not the case pomalidomide must not be dispensed.
9. You must sign, date and print your name to declare that all steps have been observed and that you authorise the prescription.

Instructions for pharmacists

A. Check that all relevant sections of the form have been fully completed by the prescriber.
   a. Counselling and effective contraceptive measures must be in place
   b. Prescription must be accompanied by a Prescription Authorisation Form
   c. For women of child bearing potential pomalidomide can only be dispensed within 7 days of the prescription date.
   d. Only one 4 weeks supply for women of childbearing potential, or 12 weeks supply for all other patients, of pomalidomide can be dispensed at any one time.
   e. The diagnosis, capsule strength and cycle number have been provided

B. Check the form does not contain confidential information (e.g. Patient Name and Hospital Number) - Originalis will not accept PAFs that do not maintain patient anonymity.

C. Check the form is complete and legible - Originalis will request that **ALL** incomplete or illegible forms are resent.

D. You must sign, date and print your name to declare that the form has been completed fully and dispensing for women of childbearing potential is taking place within 7 days of the date of prescription.

E. Complete the "Date emailed to Originalis" fields and **email** the completed forms to Originalis on **CustomerServices@originalis.eu**

Further information and materials are available from Originalis.
Pregnancy Prevention Programme: +44 (0)203 630 1688
E-mail: CustomerServices@originalis.eu

Date of preparation of text: May 2022
RMP/Originalis/Imnovid/UK/002/0522
Approved by MHRA:

IMNOVID®▼ (pomalidomide) Prescription Authorisation Form (PAF)

A newly completed copy of this form MUST accompany EVERY pomalidomide prescription. Completion of this information is mandatory to ALL patients. The completed form should be retained in pharmacy.

Name of treating Hospital

Patient Date of Birth D D M M Y Y Y Y Patient ID Number/Initials

Prescriber: (print)

Supervising physician: (print)

Diagnosis: (tick)
- ☐ **Relapsed and Refractory Multiple Myeloma**
- ☐ **Multiple Myeloma**
- Other ☐ If other please specify usage:

If this patient is being treated privately, tick here ☐

Capsule strength prescribed: (tick)	1mg ☐	2mg ☐	3mg ☐	4mg ☐
Quantity of **Capsules** per cycle prescribed:*				

Number of cycle(s) prescribed 1 ☐ 2 ☐ 3 ☐

Total number of capsules:

* Do **NOT** enter number of Packs

Please tick all boxes that apply

	TICK
Woman of non-childbearing potential (maximum 12-week supply)	
Male (maximum 12-week supply)	

	Y	N
The patient has been counselled about the teratogenic risk of treatment with pomalidomide and understands the need to use a condom if involved in sexual activity with a woman of childbearing potential not using effective contraception or if their partner is pregnant (even if the patient has had a vasectomy).		

Note to pharmacist – Do not dispense unless ticked and, for a male, Y selected

	TICK
Woman of childbearing potential (maximum 4 weeks prescription only)	

	Y	N
The patient has been counselled about the teratogenic risk of treatment, the need to avoid pregnancy, and has been on effective contraception for at least 4 weeks or committed to absolute and continuous abstinence confirmed on a monthly basis.		

Date of last negative pregnancy test D D M M Y Y Y Y

Note to pharmacist – Do not dispense pomalidomide unless negative pregnancy test was conducted within 3 days of the prescription date and dispensing is taking place within 7 days of the prescription date.

Both signatures must be present prior to dispensing IMNOVID

Prescriber's declaration

As the Prescriber, I have read and understood the Healthcare Professionals' Information Pack. I confirm the information provided on this PAF is accurate, complete and in accordance with the requirements of the PPP for pomalidomide. I confirm treatment has been initiated and is monitored under the supervision of a physician experienced in managing immunomodulatory drugs.

Sign Date D D M M Y Y Y Y

Bleep

Print

Note to pharmacist – Every prescription must be accompanied by an accurately completed PAF

Pharmacist's declaration

I am satisfied that this IMNOVID PAF has been completed fully and that I have read and understood the IMNOVID Healthcare Professionals' Information Pack.

For women of childbearing potential, dispensing will be taking place within 7 days of the date of prescription. I am dispensing no more than 4 weeks supply to women of childbearing potential and 12 weeks for males and women of non-childbearing potential.

Sign Date D D M M Y Y Y Y

Bleep

Print

Name and postcode of dispensing pharmacy

Home delivery information

Name and postcode of Home delivery company used, if applicable.

A copy of every completed PAF should be sent to Bristol-Myers Squibb (BMS) immediately after dispensing via email to: paf.uk.ire@bms.com, or fax to: 0808 100 9910

Date faxed to BMS D D M M Y Y Y Y Faxed by (Name)

Date of preparation of text: May 2022
RMP/Originals/Imnovid/UK/002/0522

Approved by MHRA:

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Date of preparation of text: May 2022
RMP/Originalis/Imnovid/UK/002/0522

IMNOVID®▼ (pomalidomide)

Pregnancy Report Form

UK

Pregnancy reports must be sent to Originalis Drug Safety IMMEDIATELY

This form must be returned to Originalis: Originalis BV., Diamantweg 4 - 1812RC, Alkmaar – The Netherlands
Phone: +44 (0)203 630 1244 · Email: drugsafety@originalis.eu

NOTE: Please use the first three letters of the month (e.g.: JAN)

Date of awareness: D D M O N Y Y Y Y

Patient Data

Sex of Patient: ○ Female ○ Male

○ Pregnancy of Patient

○ Pregnancy of Patient's Partner **OR**

○ Exposure of a Pregnant Female (complete information below)

Pregnant Woman's Initials (F, M, L): | Date of Birth: D D M O N Y Y Y Y | Age:

Patient Initials (F, M, L): (Who received drug) | Date of Birth: D D M O N Y Y Y Y | Age:

Drug Name:

Date of First Dose: D D M O N Y Y Y Y | Date of Last Dose: D D M O N Y Y Y Y

Pregnancy Initially Diagnosed By:

○ Home Urine Test

○ Office Urine Test

○ Serum Test

Date of Pregnancy Test: D D M O N Y Y Y Y | Last Menstrual Period: D D M O N Y Y Y Y

Female is Currently: ____ weeks pregnant **OR** ○ No longer Pregnant ○ Unknown

Female has Elected to: ○ Carry Pregnancy to Term | Expected Date of Delivery: D D M O N Y Y Y Y

○ Terminate Pregnancy | Date Performed or Pending: D D M O N Y Y Y Y

Reporter's Information:

Reporter's Name:	Date: D D M O N Y Y Y Y
Reporter's Contact Information/ Address:	Reporter's Signature:
	Reporter's Phone Number:
Reporter's Email Address:	Reporter's Fax Number:

Patient's Prescribing Physician's Information:

Physician's Name:	Date: D D M O N Y Y Y Y
Physician's Contact Information/ Address:	Physician's Signature:
	Physician's Phone Number:
Physician's Email Address:	Physician's Fax Number:

Originalis

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Background Information on Reason for Pregnancy

Was patient erroneously considered not to be of childbearing potential?	○ Yes	○ No
If yes, state reason for considering not to be of childbearing potential		
• Age ≥ 50 years and naturally amenorrhoeic* for ≥ 1 year *amenorrhoea following cancer therapy or during breastfeeding does not rule out childbearing potential	○ Yes	○ No
• Premature ovarian failure confirmed by a specialist gynaecologist	○ Yes	○ No
• Previous bilateral salpingo-oophorectomy, or hysterectomy	○ Yes	○ No
• XY genotype, Turner syndrome, uterine agenesis.	○ Yes	○ No
Indicate from the list below what contraception was used		
• Implant	○ Yes	○ No
• Levonorgestrel-releasing intrauterine system (IUS)	○ Yes	○ No
• Medroxyprogesterone acetate depot	○ Yes	○ No
• Tubal sterilisation (specify below)	○ Yes	○ No
○ Tubal ligation	○ Yes	○ No
○ Tubal diathermy	○ Yes	○ No
○ Tubal chips	○ Yes	○ No
• Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses	○ Yes	○ No
• Ovulation inhibitory progesterone-only pills (i.e. desogestrel)	○ Yes	○ No
• Other progesterone-only pills	○ Yes	○ No
• Combined oral contraceptive pill	○ Yes	○ No
• Other intra-uterine devices	○ Yes	○ No
• Condoms	○ Yes	○ No
• Cervical cap	○ Yes	○ No
• Sponge	○ Yes	○ No
• Withdrawal	○ Yes	○ No
• Other	○ Yes	○ No
• None	○ Yes	○ No
Indicate from the list below the reason for contraceptive failure		
• Missed oral contraception	○ Yes	○ No
• Other medication or intercurrent illness interacting with oral contraception	○ Yes	○ No
• Identified mishap with barrier method	○ Yes	○ No
• Unknown	○ Yes	○ No
• Had the patient committed to complete and continuous abstinence	○ Yes	○ No
• Was the drug started despite patient already being pregnant	○ Yes	○ No
• Did patient receive educational materials on the potential risk of teratogenicity	○ Yes	○ No
• Did patient receive instructions on need to avoid pregnancy	○ Yes	○ No

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Background Information on Reason for Pregnancy

Prenatal information

Date of Last Menstrual Period: D D M O N Y Y Y Y

Estimated Delivery Date: D D M O N Y Y Y Y

Pregnancy test

Urine Qualitative ◯	Reference Range:	Date: D D M O N Y Y Y Y
Serum Quantitative ◯	Reference Range:	Date: D D M O N Y Y Y Y

Past Obstetric History

Year of Pregnancy	Outcome				Gestational Age	Type of Delivery
Y Y Y Y	◯ Spontaneous abortion	◯ Therapeutic abortion	◯ Live birth	◯ Still birth		
Y Y Y Y	◯ Spontaneous abortion	◯ Therapeutic abortion	◯ Live birth	◯ Still birth		
Y Y Y Y	◯ Spontaneous abortion	◯ Therapeutic abortion	◯ Live birth	◯ Still birth		
Y Y Y Y	◯ Spontaneous abortion	◯ Therapeutic abortion	◯ Live birth	◯ Still birth		
Y Y Y Y	◯ Spontaneous abortion	◯ Therapeutic abortion	◯ Live birth	◯ Still birth		

Birth defects

Was there any birth defect from any pregnancy?	◯ Yes	◯ No	◯ Unknown
Is there any family history of any congenital abnormality abstinence?	◯ Yes	◯ No	◯ Unknown

If yes to either of these questions, please provide details below:

Maternal Past Medical History

Condition	Dates	Treatment	Outcome
	From: D D M O N Y Y Y Y To: D D M O N Y Y Y Y		
	From: D D M O N Y Y Y Y To: D D M O N Y Y Y Y		
	From: D D M O N Y Y Y Y To: D D M O N Y Y Y Y		
	From: D D M O N Y Y Y Y To: D D M O N Y Y Y Y		
	From: D D M O N Y Y Y Y To: D D M O N Y Y Y Y		

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Maternal Current Medical Conditions

Condition	From	Treatment
	D D M O N Y Y Y Y	
	D D M O N Y Y Y Y	
	D D M O N Y Y Y Y	
	D D M O N Y Y Y Y	
	D D M O N Y Y Y Y	
	D D M O N Y Y Y Y	
	D D M O N Y Y Y Y	

Maternal Social History

Alcohol ◯ Yes ◯ No
If yes, amount/units per day:

Tobacco ◯ Yes ◯ No
If yes, amount per day:

IV or recreational drug use ◯ Yes ◯ No
If yes, provide details:

Maternal medication during pregnancy and in 4 weeks before pregnancy

(including herbal, alternative and over the counter medicines and dietary supplements)

Medication/treatment	Dates	Indication
	Start Date: D D M O N Y Y Y Y Stop Date/Continuing: D D M O N Y Y Y Y	
	Start Date: D D M O N Y Y Y Y Stop Date/Continuing: D D M O N Y Y Y Y	
	Start Date: D D M O N Y Y Y Y Stop Date/Continuing: D D M O N Y Y Y Y	
	Start Date: D D M O N Y Y Y Y Stop Date/Continuing: D D M O N Y Y Y Y	
	Start Date: D D M O N Y Y Y Y Stop Date/Continuing: D D M O N Y Y Y Y	
	Start Date: D D M O N Y Y Y Y Stop Date/Continuing: D D M O N Y Y Y Y	

Name of person completing this form

Name:

Date: D D M O N Y Y Y Y

Signature:

UK

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For the exercise of your rights and for any questions regarding data protection you can contact Originalis, Diamantweg 4 - 1812RC, Alkmaar – The Netherlands. If you are unhappy about how Originalis is processing your personal data, you may also have the right to lodge a complaint with the supervisory authority enforcing data protection in your country.

Reporter's Signature (required):

Signature:	Date signed: D D M O N Y Y Y Y

On behalf of Originalis, thank you for providing information that will assist us in our commitment to patient safety.

IMNOVID®▼ (pomalidomide)

Event-Specific Questionnaire for HCP – Pregnancy Outcome Form
(Patient or Partner of Patient)

UK

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Phone: +44 (0)203 630 1244 · Email: drugsafety@originalis.eu

NOTE: Please use the first three letters of the month (e.g.: JAN)

Reporter information

Reporter Name:	
Address:	
City, County, Country:	
Phone No.:	
Fax No.:	

Patient information

Patient ID: ____ Date of Birth: D D M O N Y Y Y Y Ethnicity: ○ White ○ African-Caribbean ○ Other, specify below: ____

Partner of patient information

○ Not applicable Ethnicity: ○ White ○ African-Caribbean ○ Other, specify below: ____

Pregnancy outcome

Date of delivery: D D M O N Y Y Y Y Gestation age at delivery: ____

Normal	○ No	○ Yes	
C-section	○ No	○ Yes	
Induced	○ No	○ Yes	
Ectopic pregnancy	○ No	○ Yes	
Elective termination	○ No	○ Yes	Date: D D M O N Y Y Y Y
Spontaneous abortion (≤20 weeks)	○ No	○ Yes	Weeks from LMP: ____
Foetal death/stillbirth (>20 weeks)	○ No	○ Yes	
Were the products of conception examined?	○ No	○ Yes	If yes, was the foetus normal? ○ No ○ Yes ○ Unknown If no, describe below: ____

Obstetrics information

Complications during pregnancy	○ No	○ Yes	If yes, please specify ____
Complications during labour/delivery	○ No	○ Yes	If yes, please specify ____
Post-partum maternal complications	○ No	○ Yes	If yes, please specify ____

Foetal outcome

Live normal infant	○ No	○ Yes	
Foetal distress	○ No	○ Yes	
Intra-uterine growth retardation	○ No	○ Yes	
Neonatal complication	○ No	○ Yes	If yes, please specify ____
Birth defect noted?	○ No	○ Yes	If yes, please specify ____

Sex: ○ Male ○ Female **Birth weight:** ____ lbs ____ oz. or ____ kg **Length:** ____ inches or ____ cm.

Apgar score: 1 min: ____ 5 min: ____ 10 min: ____ ○ Unknown

Signature of person completing this form

Signature: ____ Date: D D M O N Y Y Y Y

Date of preparation of text: May 2022
RMP/Originalis/Imnovid/UK/002/0522
Approved by MHRA:

IMNOVID®▼ (pomalidomide)

Event-Specific Questionnaire for HCP – Pregnancy Outcome Form
(Patient or Partner of Patient)

UK

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Reporter's Signature (required):

Signature:	Date signed: D D M O N Y Y Y Y

On behalf of Originalis, thank you for providing information that will assist us in our commitment to patient safety.

Originalis

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Approved by MHRA:

IMNOVID®▼ (pomalidomide)

Adverse Event Form

UK

This form must be returned to Originalis: Originalis BV., Diamantweg 4 - 1812RC, Alkmaar – The Netherland
Phone: +44 (0)203 630 1244 · Email: drugsafety@originalis.eu

NOTE: Please use the first three letters of the month (e.g.: JAN)

Case No:

○ New ○ Follow-up

For Originalis use only

Date of receipt: DD MON YYYY

Received by: (Name and organisation – eg CRO, or company representative)

Source: ○ Spontaneous ○ Comp. Use ○ Lit. ○ Other, Specify

For Studies Enter

Protocol:

Site Number:

Patient number:

Suspect Drug

Drug, Dosage-form, Strength, Route (eg. Tab 5mg, oral)	Dose & frequency	Lot/ Batch no.	Therapy start date: DD/MON/YYYY	Therapy stop date: DD/MON/YYYY	Drug-Event Causal relationship Other, Specify (Causal relationship 1 = Not related, 2 = Related)	Indication for use of drug
			/ /	/ /		
			/ /	/ /		
			/ /	/ /		
			/ /	/ /		
			/ /	/ /		

Action Taken

○ None ○ Unknown ○ Not applicable
○ Dose decreased, specify ○ Permanently discontinued
○ Dose increased, specify ○ Temporarily interrupted

Patient Data

Initials: Date of Birth: DD MON YYYY Age:

Weight: kg Height: cm Gender ○ Male ○ Female

Adverse Event

Description of Adverse Event (provide diagnosis if available) - symptoms and treatment:

Event onset date: DD MON YYYY

Event stop date: DD MON YYYY

Outcome of Adverse Event

○ Recovered
○ Recovered with sequelae
○ Not recovered
○ Unknown
○ Death

Date of death: DD MON YYYY

Cause(s) of death:

Did the event result in hospitalisation or prolonged hospitalisation? ○ Yes ○ No

If autopsy is performed please forward report.
Please attach relevant clinical laboratory assessments to confirm the event

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Adverse Event Form

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NOTE: Please use the first three letters of the month (e.g.: JAN)

Case No:	

Medical History

◯ Yes (if yes, please specify)
◯ None
◯ Unknown

Other Medication (Medication taken in the last 3 months prior to the event)

Drug, Dosage-form, Strength, Route (eg. Tab 5mg, oral)	Dose & frequency	Therapy start date: *DD/MON/YYYY*	Therapy stop date: *DD/MON/YYYY*	Indication for use of drug
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Has the patient discussed this event with their healthcare professional?
◯ Yes (If yes, would you please provide their healthcare professional's contact information below?)
◯ No ◯ Unknown

Healthcare professional's contact information

Name:		Fax:	
Address:		Phone:	
		Email:	
Country:			

Reporter

◯ Physician ◯ Nurse ◯ Pharmacist ◯ Patient ◯ Relative ◯ Other, please specify

Name:		Fax:	
Address:		Phone:	
		Email:	
Country:			

Pharmacy Name (if applicable)

Name:		Email:	

Signature

Sign:		Date of AE awareness:	*DD*	*MON*	*YYYY*

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Case No:	

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This section applies only if the reporter is the patient or anyone but the prescriber/physician/HCP
Please chose one, as applicable:

◯ I grant Originalis permission to contact the prescriber/physician/HCP who treated me/the affected patient when the side effect(s) occurred and authorise him/her to provide data from my medical record related to the event(s) occurred.

◯ No, I do not grant Originalis permission to contact the prescriber/physician/HCP who treated me/the patient.

If you grant Originalis permission, please provide the information of the prescriber/physician/HCP

Contact information

Name:		Fax:	
Address:		Phone:	
		Email:	
Country:			

Date of preparation of text: May 2022
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Date of preparation of text: May 2022
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COMBINED CHECKLIST FOR COMMENCING IMNOVID®▼ (pomalidomide) TREATMENT

This checklist is to assist you with counselling a patient before they commence pomalidomide treatment in order to assure it is used safely and correctly. Please choose the applicable column for the risk category of the patient and refer to the counselling messages provided.

Counselling	Women of Childbearing Potential	Women of Non–Childbearing Potential*	Male
Inform of expected teratogenic risk to the unborn child	●	●	●
Inform of the need for effective contraception** for at least 4 weeks before starting treatment, throughout the entire duration of treatment, including during treatment interruptions, and for at least 4 weeks after the end of treatment, or absolute and continued abstinence	●		
Inform that even if patient has amenorrhoea they must comply with advice on contraception	●		
Confirm patient is capable of complying with contraceptive measures	●		●
Inform of the expected consequences of pregnancy and the need to consult rapidly if there is a risk of pregnancy	●		●
Inform of the need to stop treatment immediately if female patient is suspected to be pregnant	●		
Confirm patient agrees to undergo pregnancy testing at least in 4 weekly intervals unless confirmed tubal sterilisation	●		
Inform of hazards and necessary precautions associated with use of pomalidomide	●	●	●
Inform patient not to share medication	●	●	●
Inform to return unused capsules to pharmacist	●	●	●
Inform not to donate blood whilst taking pomalidomide, during treatment interruptions and for at least 7 days following discontinuation	●	●	●
Inform of the need to use condoms, including those who have had a vasectomy as seminal fluid may still contain pomalidomide in the absence of spermatozoa, throughout treatment duration, during dose interruption, and for at least 7 days after cessation of treatment if partner is pregnant or of childbearing potential not using effective contraception			●
Inform of the need not to donate semen or sperm during treatment, during dose interruptions, and for at least 7 days following discontinuation			●
Inform about the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with pomalidomide	●	●	●
Inform about which are effective contraceptive methods that she or the female partner of a male patient can use	●		●
Inform that if his female partner becomes pregnant whilst he is taking pomalidomide or shortly after he has stopped taking pomalidomide, he should inform his prescriber immediately and that it is recommended to refer the female partner to a physician specialised or experienced in teratology for evaluation and advice			●

* Refer to Healthcare Professional brochure for criteria to determine if patient is a woman of non–childbearing potent

** Refer to Healthcare Professional brochure for information on contraceptionial.

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Contraceptive referral	Women of Childbearing Potential	Women of Non–Childbearing Potential*	Male
Contraceptive referral required	●		
Contraceptive referral made	●		
Contraceptive consultation completed	●		

Contraception Patient is currently established on one of the following for at least 4 weeks	Women of Childbearing Potential	Women of Non–Childbearing Potential*	Male
Implant	●		
Levonorgestrel-releasing intrauterine system (IUS)	●		
Medroxyprogesterone acetate depot	●		
Sterilisation	●		
Sexual intercourse with a vasectomised male partner only: vasectomy must be confirmed by negative semen analysis	●		
Ovulation inhibitory progesterone-only pill (desogestrel)	●		
Patient commits to complete and absolute abstinence	●		
Negative pregnancy test before starting treatment	●		

Not of childbearing potential One of the following criteria have been met to determine patient is women NCBP	Women of Childbearing Potential	Women of Non–Childbearing Potential*	Male
Age ⩾50 years and naturally amenorrhoeaic*** for ⩾1 year not induced by chemotherapy		●	
Premature ovarian failure confirmed by specialist gynaecologist		●	
Bilateral salpingo-oophorectomy, or hysterectomy		●	
XY genotype, Turner syndrome, uterine agenesis		●	

* Refer to Healthcare Professional brochure for criteria to determine if patient is a woman of non-childbearing potential.

** Refer to Healthcare Professional brochure for information on contraception

***Amenorrhoea following cancer therapy or during breastfeeding does not rule out childbearing potential

TREATMENT FOR A WOMAN OF CHILDBEARING POTENTIAL CANNOT START UNTIL PATIENT IS ESTABLISHED ON AT LEAST ONE EFFECTIVE METHOD OF CONTRACEPTION FOR AT LEAST 4 WEEKS PRIOR TO INITIATION OF THERAPY OR COMMITS TO ABSOLUTE AND CONTINUOUS ABSTINENCE AND PREGNANCY TEST IS NEGATIVE.

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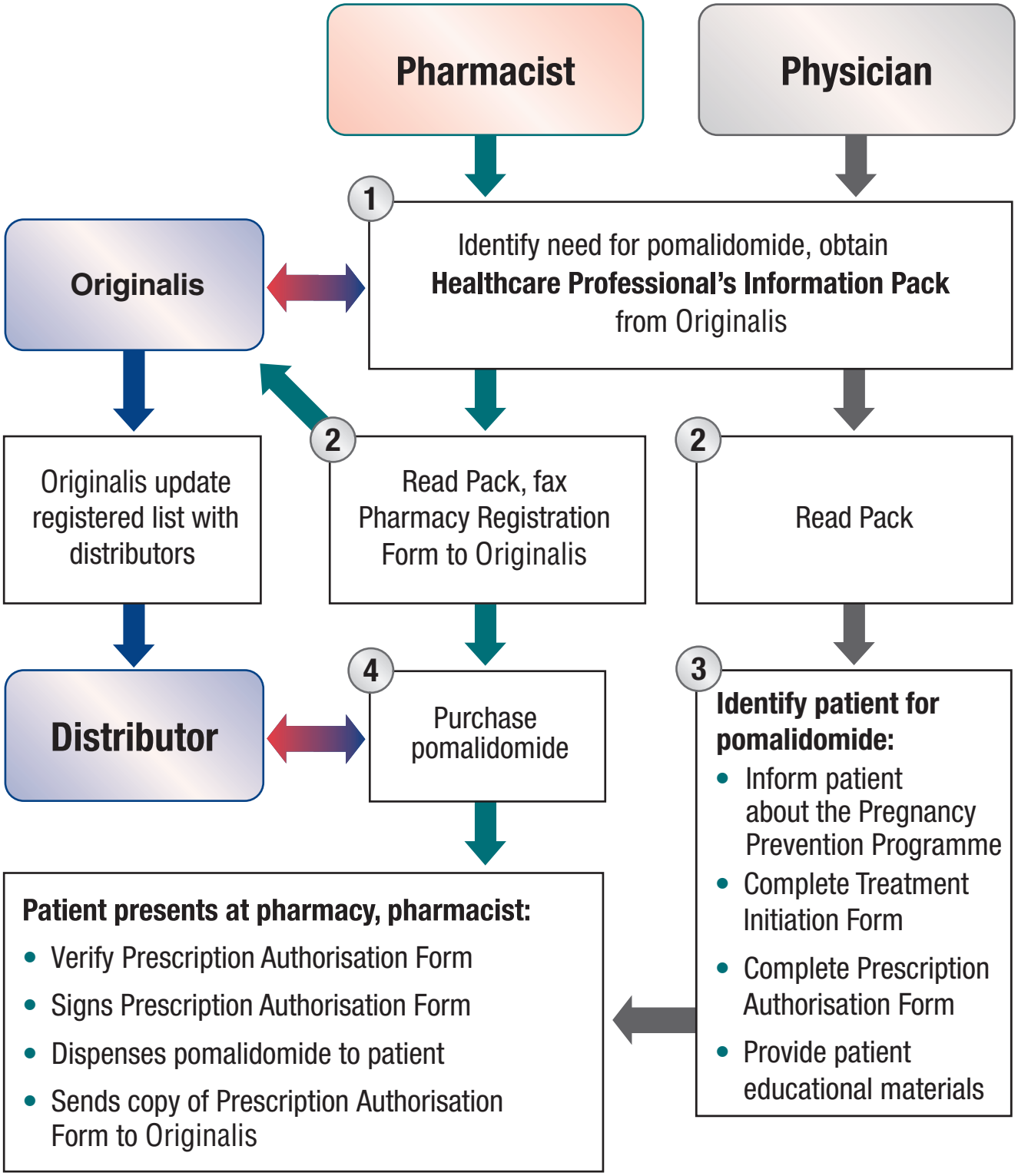
Pharmacy registration and dispensing of IMNOVID®▼ (pomalidomide)

UK



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Frequently asked questions (FAQs)

UK

Where can I get further copies of the IMNOVID® ▼ (pomalidomide) Healthcare Professional's Information Pack or the patient materials?

If you would like further copies of the IMNOVID Healthcare Professional's Information Pack or any other materials for healthcare professionals or patients, please telephone or e-mail Originalis using the contact details below, or by speaking to any Originalis representative.

Tel: +44 (0)203 630 1688
Email: customerservices@originalis.eu

What must I do prior to ordering or dispensing pomalidomide?

All pharmacies must register with Originalis prior to ordering or dispensing pomalidomide. You will need to register the dispensing pharmacy using the Pharmacy Registration Form. This form is contained within this pack.
Completed Pharmacy Registration Forms should be sent via e-mail (customerservices@originalis.eu).
Once you have returned a completed Pharmacy Registration Form, we will inform the distributors who will place you on the registered list.

Do I need a registration number to order pomalidomide?

No, you just need to register with Originalis by returning the Pharmacy Registration Form. We will register you and inform the distributor that you are registered and can receive pomalidomide.

Where do I order pomalidomide?

Once registered, to order pomalidomide please contact Originalis in the order Customer Service. You must have returned the Pharmacy Registration Form to Originalis before you can place an order. You will need to email your order to the distributors (all orders must be received in writing).

Distributor: Customer Service
Tel: +44 (0)203 630 1688
Email: customerservices@originalis.eu

How should I report an Adverse Event or suspected pregnancy?

Adverse Events or suspected pregnancies should be reported to Originalis Drug Safety. Adverse event reporting forms, pregnancy reporting forms and pregnancy outcome forms are included in this Healthcare Professional's Information Pack. Completed forms should be forwarded to the Originalis Drug Safety using the contact details below:

Tel: +44 (0)203 630 1244
Email: DrugSafety@originalis.eu

Adverse evens can also be reported online using the Yellow Card Scheme via www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary);
- by emailing yellowcard@mhra.gov.uk;
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789;
- or by downloading and printing a form from the Yellow Card section of the MHRA website.

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Frequently asked questions (FAQs)

UK

What are the contact details for Originalis Medical Information?

To contact Originalis in the UK for Medical Information, please telephone or email the Medical Information department using the contact details below:

Tel: +44 (0)203 630 1244
Email: MedInfo@originalis.eu

Adverse evens can also be reported online using the Yellow Card Scheme via www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary);
- by emailing yellowcard@mhra.gov.uk;
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789;
- or by downloading and printing a form from the Yellow Card section of the MHRA website.

How will Originalis audit pharmacies registered for the IMNOVID Pregnancy Prevention Programme?

Originalis audits will be performed remotely as an ongoing process, using the information supplied on the Prescription Authorisation Forms, and the collated results will be shared with the MHRA. Originalis will contact the pharmacy in cases where there are irregularities or queries on Prescription Authorisation Forms so that any potential problems or errors can be dealt with as they arise. The Prescription Authorisation Forms must be sent to Originalis for every cycle of pomalidomide treatment for all patients, to allow audit obligations (which were agreed by the Chief Pharmacist when they signed the Pharmacy Registration Form) to be effectively fulfilled by Originalis collating the data from the Prescription Authorisation Forms you have supplied. It is therefore critical that Prescription Authorisation Forms are completed fully and accurately. All the information will be provided, in an anonymised and aggregated format within the annual audit reports, to the MHRA.

Where do I send my Prescription Authorisation Forms?

Please contact the Medical Information Team on the following contact details:

Originalis BV.
Diamantweg 4
1812RC, Alkmaar
The Netherlands

Tel: +44 (0)203 630 1688
Email: CustomerServices@originalis.eu

If you wish to use email, please scan the completed form and email it as an attachment.

Please keep a copy of the Prescription Authorisation Forms for your records.

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Contact details

UK

Medical Information:

For Information and questions on the Pregnancy prevention Programme, pharmacy registrations and other medical information queries
Tel: +44 (0)203 630 1244
Email: MedInfo@originalis.eu

Drug Safety:

To report any adverse events to Originalis.
Tel: +44 (0)203 630 1244
Email: drugsafety@originalis.eu

Adverse events can also be reported online using the Yellow Card Scheme via www.mhra.gov.uk/yellowcard or by searching for MHRA Yellow Card in the Google Play or Apple App Store. Alternatively, prepaid Yellow Cards for reporting are available:

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