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Package leaflet: Information for the patient

Revlimid 2.5 mg hard capsules, Revlimid 5 mg hard capsules, Revlimid 7.5 mg hard capsules, Revlimid 10 mg hard capsules, Revlimid 15 mg hard capsules, Revlimid 20 mg hard capsules

lenalidomide

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You may help by reporting any side effects you may get.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
If you have any further questions, ask your doctor or pharmacist.
This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

What is in this leaflet
1. What Revlimid is and what it is used for
2. What you need to know before you take Revlimid
3. How to take Revlimid
4. Possible side effects
5. How to store Revlimid
6. Contents of the pack and other information

1. What Revlimid is and what it is used for

What Revlimid is
Revlimid contains the active substance 'lenalidomide'. This medicine belongs to a group of medicines which affect how your immune system works.

What Revlimid is used for
Revlimid is used in adults for:
Multiple myeloma
Myelodysplastic syndromes
Mantle cell lymphoma
Follicular lymphoma

Multiple myeloma
Multiple myeloma is a type of cancer which affects a certain kind of white blood cell, called the plasma cell. These cells collect in the bone marrow and divide, becoming out of control.

Do not take Revlimid:
If you are pregnant, think you may be pregnant or are planning to become pregnant, as Revlimid is expected to be harmful to an unborn child (see section 2, 'Pregnancy, breast-feeding and contraception' - information for women and men).

Newly diagnosed multiple myeloma - in patients who have had a bone marrow transplant
Revlimid is used on its own as a maintenance therapy after patients have recovered enough following a bone marrow transplant.

Newly diagnosed multiple myeloma - in patients who cannot have a bone marrow transplant
Revlimid is taken with other medicines. These may include:
a chemotherapy medicine called ' bortezomib'
an anti-inflammatory medicine called ' dexamethasone'
a chemotherapy medicine called ' melphalan' and
an immunosuppressant medicine called ' prednisone'.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Revlimid if:
you will take these other medicines at the start of treatment and then continue to take Revlimid on its own.

Multiple myeloma - in patients who have had treatment before
Revlimid is taken together with an anti-inflammatory medicine called 'dexamethasone'.

Revlimid can stop the signs and symptoms of multiple myeloma getting worse. It has also been shown to delay multiple myeloma from coming back following treatment.

Myelodysplastic syndromes (MDS)
MDS are a collection of many different blood and bone marrow diseases. The blood cells become abnormal and do not function properly.

Revlimid is used alone to treat adult patients who have been diagnosed with MDS, when all of the following apply:
you need regular blood transfusions (to treat low levels of red blood cells (transfusion-dependent anaemia)
you have an abnormality of cells in the bone marrow called an 'isolated deletion 5q cytogenetic abnormality'. This means your body does not make enough healthy blood cells

Revlimid can increase the number of healthy red blood cells that the body produces by reducing the number of abnormal cells:
This can reduce the number of blood transfusions needed. It is possible that no transfusions will be needed.

Mantle cell lymphoma (MCL)
MCL is a cancer of part of the immune system (the lymph tissue). It affects a type of white blood cell called B-lymphocytes or B-cells. MCL is a disease where B-cells grow in an uncontrolled way and build up in the lymph tissue, bone marrow or blood.

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Follicular lymphoma (FL)
FL is a slow growing cancer that affects the B-lymphocytes. These are a type of white blood cells that help your body fight infection.

Revlimid is taken together with another medicine called 'rituximab' for the treatment of adult patients with previously treated follicular lymphoma.

How Revlimid works
Revlimid works by affecting the body's immune system and directly attacking the cancer. It works in a number of different ways:
by stopping the cancer cells developing
by stopping blood vessels growing in the cancer
by stimulating part of the immune system to attack the cancer cells.

2. What you need to know before you take Revlimid
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you have experienced in the past a combination of any of the following symptoms: widespread rash, red skin, high body temperature, flu-like symptoms, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes - these are signs of a severe skin reaction called Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome. (see also section 4 "Possible side effects").

If any of the above apply to you, tell your doctor, pharmacist or nurse before starting treatment.

At any time during or after your treatment, tell your doctor or nurse immediately if you:
experience blurred, loss of or double vision, difficulty speaking, weakness in an arm or a leg, a change in the way you walk or problems with your balance, persistent numbness, decreased sensation or loss of sensation, memory loss or confusion. These may all be symptoms of a serious and potentially fatal brain condition known as progressive multifocal leukoencephalopathy (PML). If you had these symptoms prior to treatment with Revlimid, tell your doctor about any change in these symptoms.

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some medicines used for heart problems - such as digoxin
some medicines used to thin the blood - such as warfarin.

Pregnancy, breast-feeding and contraception - information for women and men
Pregnancy
For women taking Revlimid
You must not take Revlimid if you are pregnant, as it is expected to be harmful to an unborn baby

How and when to take Revlimid
swallow the capsules whole, preferably with water.
do not break, open or chew the capsules. If powder from a broken Revlimid capsule makes contact with the skin, wash the skin immediately and thoroughly with soap and water.

For men taking Revlimid
If your partner becomes pregnant whilst you are taking Revlimid, you should inform your doctor immediately. It is recommended that your partner seeks medical advice.

Breast-feeding
You must not breast-feed when taking Revlimid, as it is not known if Revlimid passes into breast milk.

Contraception
For women taking Revlimid
Before starting treatment, ask your doctor if you are able to become pregnant, even if you think this is unlikely.

For patients with MDS taking Revlimid
If you have MDS, you may be more likely to get a more advanced condition called acute myeloid leukaemia (AML). In addition, it is not known how Revlimid affects the chance of you getting AML.

How Revlimid works
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Multiple myeloma - in patients who have had treatment before
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Revlimid can stop the signs and symptoms of multiple myeloma getting worse. It has also been shown to delay multiple myeloma from coming back following treatment.

After completing every 28-day cycle, you should start a new 'cycle' over the next 28 days.

How much Revlimid to take
Before you start treatment, your doctor will tell you:
how much Revlimid you should take
how many days of your treatment cycle to take each medicine.

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FRONT SIDE

Uncommon side effects (may affect up to 1 in 100 people):
Bleeding within the skull
Circulatory problems
Loss of vision
Loss of sex drive (libido)
Passing large amounts of urine with bone pain and weakness, which may be symptoms of a kidney disorder (Fanconi syndrome)

Yellow pigmentation to the skin, mucus membrane or eyes (jaundice), pale coloured stools, dark coloured urine, skin itch, rash, pain or swelling of the stomach - these may be symptoms of injury to the liver (hepatic failure)

Stomach pain, bloating, or diarrhoea, which may be symptoms of inflammation in the large intestine (called colitis or caecitis)

Damage to the cells of the kidney (called renal tubular necrosis)

Changes to the colour of your skin, sensitivity to sunlight

Tumour lysis syndrome - metabolic complications that can occur during treatment of cancer and sometimes even without treatment. These complications are caused by the break-down products of dying cancer cells and may include the following: changes to blood chemistry: high potassium, phosphorus, uric acid, and low calcium consequently leading to changes in kidney function, heart beat, seizures, and sometimes death.

Increase in blood pressure within blood vessels that supply the lungs (pulmonary hypertension).

Not known side effects (frequency cannot be estimated from the available data):
Sudden, or mild but worsening pain in the upper stomach and/or back, which remains for a few days, possibly accompanied by nausea, vomiting, fever and a rapid pulse - these symptoms may be due to inflammation of the pancreas.

Swallowing, shortness of breath or a dry cough, which may be symptoms caused by inflammation of the tissue in the lungs.

Rare cases of muscle breakdown (muscle pain, weakness or swelling) which can lead to kidney problems (metabolic myopathy) have been observed, some of them when Revlimid is administered with a statin (a type of cholesterol lowering medicine).

A condition affecting the skin caused by inflammation of small blood vessels, along with pain in the joints and fever (leukoerythrocytic vasculitis).

Breakdown of the wall of the stomach or gut (perforation of the stomach or intestine). This may lead to very serious infection. Tell your doctor if you have severe stomach pain, fever, nausea, vomiting, blood in your stool, or changes in bowel habits.

Viral infections, including herpes zoster (also known as 'shingles', a viral disease that causes a painful skin rash with blisters) and recurrence of hepatitis B infection (which can cause yellowing of the skin and eyes, dark brown-coloured urine, right-sided stomach pain, fever and feeling nauseous or being sick).

Rejection of solid organ transplant (such as kidney, heart, lung, liver or pancreas).

Reporting of side effects
If you get any side effects not listed in this leaflet, you can also report side effects directly 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Revlimid

- Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date, which is stated on the blister and on the carton after EXP. The expiry date refers to the last day of that month.
This product does not require any special storage conditions.
Do not use this medicine if you notice any damage or signs of tampering to the pack.
Do not throw away any medicines via wastewater or household waste. Please return unused medicines to your pharmacist. These measures will help protect the environment.

6. Contents of the pack and other information

Revlimid 2.5 mg hard capsules:
The active substance is lenalidomide. Each capsule contains 2.5 mg of lenalidomide.

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