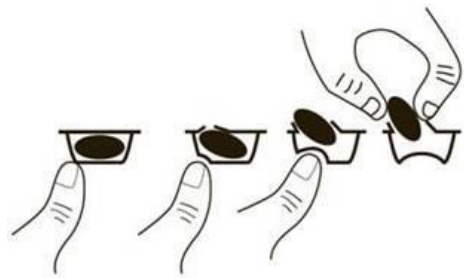


If you suffer from liver or kidney problems your doctor will check your condition very carefully whilst you are receiving this medicine.

How to take Imnovid

- Do not break, open or chew the capsules. If powder from a broken capsule makes contact with the skin, wash the skin immediately and thoroughly with soap and water.
- Healthcare professionals, caregivers and family members 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.
- Swallow the capsules whole, preferably with water.
- You can take the capsules either with or without food.
- Take your capsules at about the same time each day.

To remove the capsule from the blister, press only one end of the capsule out to push it through the foil. Do not apply pressure on the centre of the capsule as this can cause it to break.



Your doctor will advise you of how and when to take Imnovid if you have kidney problems and are receiving dialysis treatment.

Duration of the treatment with Imnovid

You should continue the cycles of treatment until your doctor tells you to stop.

If you take more Imnovid than you should

If you take more Imnovid than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

If you forget to take Imnovid

If you forget to take Imnovid on a day when you should, take your next capsule as normal the next day. Do not increase the number of capsules you take to make up for not taking Imnovid the previous day.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

Stop taking Imnovid and see a doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

- Fever, chills, sore throat, cough, mouth ulcers or any other signs of infection (due to less white blood cells, which fight infection).
- Bleeding or bruising without a cause, including nosebleeds and bleeding from the bowels or stomach (due to effects on blood cells called 'platelets').
- Rapid breathing, rapid pulse, fever and chills, passing very little to no urine, nausea and vomiting, confusion, unconsciousness (due to infection of blood called sepsis or septic shock).
- Severe, persistent or bloody diarrhoea (possibly with stomach pain or fever) caused by bacteria called *Clostridium difficile*.
- Chest pain, or leg pain and swelling, especially in your lower leg or calves (caused by blood clots).

- Shortness of breath (from serious chest infection, inflammation of the lung, heart failure or blood clot).
- Swelling of face, lips, tongue and throat, which may cause difficulty breathing (due to serious types of allergic reaction called angioedema and anaphylactic reaction).
- Certain types of skin cancer (squamous cell carcinoma and basal cell carcinoma), which can cause changes in the appearance of your skin or growths on your skin. If you notice any changes to your skin whilst taking Imnovid, tell your doctor as soon as possible.
- Recurrence of hepatitis B infection, which can cause yellowing of the skin and eyes, dark brown-coloured urine, right-sided abdominal pain, fever and feeling nauseous or being sick. Tell your doctor straightaway if you notice any of these symptoms.
- Widespread rash, high body temperature, enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome, Toxic Epidermal Necrolysis or Stevens-Johnson Syndrome). Stop using pomalidomide if you develop these symptoms and contact your doctor or seek medical attention immediately. See also section 2.

Stop taking Imnovid and see a doctor straight away

if you notice any of the serious side effects listed above – you may need urgent medical treatment.

Other side effects

Very common (may affect more than 1 in 10 people):

- Shortness of breath (dyspnoea).
- Infections of the lungs (pneumonia and bronchitis).
- Infections of the nose, sinuses and throat, caused by bacteria or viruses.
- Flu-like symptoms (influenza).
- Low red blood cells, which may cause anaemia leading to tiredness and weakness.
- Low blood levels of potassium (hypokalaemia), which may cause weakness, muscle cramps, muscle aches, palpitations, tingling or numbness, dyspnoea, mood changes.
- High blood levels of sugar.
- A fast and irregular heartbeat (atrial fibrillation).
- Loss of appetite.
- Constipation, diarrhoea or nausea.
- Being sick (vomiting).
- Abdominal pain.
- Lack of energy.
- Difficulty in falling asleep or staying asleep.
- Dizziness, tremor.
- Muscle spasm, muscle weakness.
- Bone pain, back pain.
- Numbness, tingling or burning sensation to the skin, pains in hands or feet (peripheral sensory neuropathy).
- Swelling of the body, including swelling of the arms or legs.
- Rashes.
- Urinary tract infection, which may cause a burning sensation when passing urine, or a need to pass urine more often.

Common (may affect up to 1 in 10 people):

- Fall.
- Bleeding within the skull.
- Decreased ability to move or feel (sensation) in your hands, arms, feet and legs because of nerve damage (peripheral sensorimotor neuropathy).
- Numbness, itching, and a feeling of pins and needles on your skin (paraesthesia).
- A spinning feeling in your head, making it difficult to stand up and move normally.
- Swelling caused by fluid.
- Hives (urticaria).
- Itchy skin.
- Shingles.
- Heart attack (chest pain spreading to the arms, neck, jaw, feeling sweaty and breathless, feeling sick or vomiting).
- Chest pain, chest infection.
- Increased blood pressure.
- A fall in the number of red and white blood cells and platelets at the same time (pancytopenia), which will make you more prone to bleeding and bruising. You may feel tired and weak, and short of breath and you

are also more likely to get infections.

- Decreased number of lymphocytes (one type of white blood cells) often caused by infection (lymphopenia).
- Low blood levels of magnesium (hypomagnesaemia), which may cause tiredness, generalised weakness, muscle cramps, irritability and may result in low blood levels of calcium (hypocalcaemia), which may cause numbness and, or tingling of hands, feet, or lips, muscle cramps, muscle weakness, light-headedness, confusion.
- Low blood level of phosphate (hypophosphataemia), which may cause muscle weakness and irritability or confusion.
- High blood level of calcium (hypercalcaemia), which may cause slowing reflexes and skeletal muscle weaknesses.
- High blood levels of potassium, which may cause abnormal heart rhythm.
- Low blood levels of sodium, which may cause tiredness and confusion, muscle twitching, fits (epileptic seizures) or coma.
- High blood levels of uric acid, which may cause a form of arthritis called gout.
- Low blood pressure, which may cause dizziness or fainting.
- Sore or dry mouth.
- Changes in the way things taste.
- Swollen abdomen.
- Feeling confused.
- Feeling down (depressed mood).
- Loss of consciousness, fainting.
- Clouding of your eye (cataract).
- Damage to the kidney.
- Inability to pass urine.
- Abnormal liver test.
- Pain in the pelvis.
- Weight loss.

Uncommon (may affect up to 1 in 100 people):

- Stroke.
- Inflammation of the liver (hepatitis) which can cause itchy skin, yellowing of the skin and the whites of the eyes (jaundice), pale coloured stools, dark coloured urine and abdominal pain.
- The breakdown of cancer cells resulting in the release of toxic compounds into the bloodstream (tumour lysis syndrome). This can result in kidney problems.
- Underactive thyroid gland, which may cause symptoms such as tiredness, lethargy, muscle weakness, slow heart rate, weight gain.

Not known (frequency cannot be estimated from the available data):

- Rejection of solid organ transplant (such as heart or liver).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible 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 Imnovid

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 carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not use Imnovid if you notice any damage or signs of tampering to medicine packaging.

Do not throw away any medicines via wastewater or household waste. Any unused medicine should be returned to the pharmacist at the end of treatment.

These measures will help protect the environment.

If the medicine becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

6. Contents of the pack and other information

What Imnovid contains

- The active substance is pomalidomide.
- The other ingredients are mannitol (E421), starch, pregelatinised, and sodium stearyl fumarate.

Imnovid 1 mg hard capsule:

- Each capsule contains 1 mg of pomalidomide.
- The capsule shell contains: gelatin, titanium dioxide (E171), indigotine (E132) and yellow iron oxide (E172) and white and black ink.
- The printing ink contains: shellac, titanium dioxide (E171), simeticone, propylene glycol (E1520) and ammonium hydroxide (E527) (white ink) and shellac, iron oxide black (E172), propylene glycol (E1520) and ammonium hydroxide (E527) (black ink).

Imnovid 2 mg hard capsule:

- Each capsule contains 2 mg of pomalidomide.
- The capsule shell contains: gelatin, titanium dioxide (E171), indigotine (E132), yellow iron oxide (E172), erythrosin (E127) and white ink.
- The printing ink contains: white ink - shellac, titanium dioxide (E171), simeticone, propylene glycol (E1520) and ammonium hydroxide (E527).

What Imnovid looks like and contents of the pack

Imnovid 1 mg hard capsules: Dark blue opaque cap and yellow opaque body, with "POML 1 mg" written on them.

Imnovid 2 mg hard capsules: Dark blue opaque cap and orange opaque body, with "POML 2 mg" written on them.

Each pack contains 21 capsules.

Manufacturer

Celgene Distribution B.V.
Orteliuslaan 1000
3528 BD Utrecht
Netherlands

or

Celgene Europe B.V.
Winthontlaan 6 N
3526 KV Utrecht
Netherlands

Procured from within the EU and repackaged for the PL Holder:
Abacus Medicine Ltd., Abbey House,
282 Farnborough Road, Farnborough,
GU14 7NA, United Kingdom

Imnovid® 1 mg hard capsules PL 45763/0787
Imnovid® 2 mg hard capsules PL 45763/0789

POM

Imnovid® is a registered trademark of Celgene Corporation.

This leaflet was last revised on 25.04.2025.

For any information about this medicine, please contact the local representative of the Product Licence Holder: Abacus Medicine Ltd., tel: +44(0)2036301244, email: MedInfo@abacusmedicine.co.uk or drugsafetyuk@abacusmedicine.co.uk

Blind or partially sighted? Is this leaflet hard to see or read? Call 02036301310 or write to info@abacusmedicine.com to obtain the leaflet in a format suitable for you.