

Innovid[®] (pomalidomide)
Brochure for Male Patients

Summary

- Imnovid[®] is the trade name for pomalidomide.
- 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.
- Ask your doctor to inform you on which are the effective contraceptive methods that your female partner can use.
- You should never share Imnovid[®] 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 and for 7 days after treatment finishes, this includes dose interruptions.
- You should not donate semen or sperm during treatment and for 7 days after treatment finishes, this includes dose interruptions.
- If you experience any side effects whilst taking Imnovid[®] you should tell your doctor.
- For additional information, please refer to the Patient Leaflet.

Safety Information for all Patients

- You must never take Imnovid[®] if:
 - You are allergic to Imnovid[®] or to any of the other ingredients contained in the capsule.
- Pomalidomide is structurally related to thalidomide, which is known to cause severe, life-threatening birth defects.
- Imnovid[®] is expected to be harmful to an unborn baby.
- Ask your doctor to inform you on which are the effective contraceptive methods that your female partner can use.

Side effects

Like all medicines, Imnovid[®] can cause side-effects, although not everybody gets them. Some are more common than others and some are more serious than others. Ask your doctor or pharmacist if you would like more information, and refer to the Package Leaflet. Almost all 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 doctor. It is important that you talk to your doctor if you have any side-effects during Imnovid[®] treatment.

Blood clots and infections

Imnovid[®] treatment may increase the risk of you developing blood clots in some veins and arteries ("thromboembolic events") in the body. People with myeloma may already have a higher risk of blood clots. Symptoms of a blood clot can be leg pains, swelling and redness of the lower legs or arms. This may be due to blood clots in the veins of your leg (deep vein thrombosis). Sometimes the clots can travel in your bloodstream to your lungs producing symptoms of chest pain and breathlessness.

Therefore you must tell your doctor immediately if you experience:

- any fever, chills, sore throat, cough, mouth ulcers or any other signs of infection (due to reduced number of white blood cells, which fight infection)
- any bleeding or bruising in the absence of injury
- any chest or leg pain and swelling, especially in your lower leg or calves
- any shortness of breath.

You may be prescribed treatment to help prevent blood clots from forming.

If you have any risk factors for developing thromboembolic events, e.g. smoking, high blood pressure, high cholesterol, a clotting disorder, a previous blood clot (in a vein or artery), you should tell your doctor.

Damage to nerves in the hands and feet

Imnovid[®] treatment may increase the risk of you developing damage to nerves in the hands and feet ("peripheral neuropathy"). Many of the treatments for myeloma can cause damage to nerves in the hands and feet, or make current symptoms worse.

Therefore you must tell your doctor immediately if you experience:

- any tingling sensation or numbness to pain
- any muscle weakness
- any spasms

Feeling confused or less alert

You should avoid situations where feeling confused or less alert may be a problem and you should first seek medical advice before taking other medicinal products known to cause feeling confused or less alert. You can reduce impact by taking pomalidomide at night.

What should you tell your doctor before taking Imnovid[®]

- If your partner is pregnant, or if you think your partner may be pregnant or if your partner is planning to become pregnant, as Imnovid[®] may be harmful to an unborn child.
- 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 Imnovid[®] capsules. Ask your pharmacist for advice.
- If you have a history of kidney problems.
- If you have a history of liver problems.
- 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.

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.

Imnovid[®]

- Your doctor will prescribe a dose of Imnovid[®] suited to you
- Imnovid[®] is taken orally (by mouth) usually once each day for 21 days followed by a 7-day rest. The total 28 days is called a cycle
- Your doctor 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 doctor has prescribed. If in doubt, ask your doctor or pharmacist for advice
- Imnovid[®] capsules should be swallowed whole, with a glass of water, can be taken with or without food
- Imnovid[®] can be taken at any time of day but it should be taken at approximately the same time each day

Dexamethasone

- Imnovid[®] is licensed to be taken in combination with dexamethasone and therefore you are likely to receive both
- If you are also taking dexamethasone tablets you can take these at the same time as your Imnovid[®]
- Dexamethasone is usually only taken for a few days each week. Follow the instructions from your doctor/pharmacist carefully

What to do if you have taken more than the prescribed dose of Imnovid[®]:

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

Taking other medicines

Please tell your doctor 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 doctor or other healthcare professional for treatment (your dentist for example) you should tell them that you are taking Innovid[®] and dexamethasone.

How to store Innovid[®] safely

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

End of Treatment Requirements

After completing your Innovid[®] treatment, it is important that:

- You return any unused Innovid[®] capsules to your pharmacist
- You do not donate blood for 7 days.
- You do not donate semen or sperm for 7 days
- If you have been using an effective pregnancy prevention method, you must continue doing so for 7 days
- If your female partner has been using an effective pregnancy prevention method, she must continue doing so for 4 weeks.

Pregnancy Prevention Programme

- Prior to treating you with Innovid[®], you will be asked to sign a Treatment Initiation Form to confirm that the benefits and risks of Innovid[®] therapy have been explained to you and that you have understood and agree to comply with the requirements of the Risk Management Plan.
- In order to ensure that an unborn baby is not exposed to Innovid[®], your doctor will complete a Patient Card documenting that you have been informed of the requirement for your partner NOT to become pregnant during treatment with Innovid[®] and for one month after you finish Innovid[®]. Your doctor will provide you with a copy of the Patient Card.
- You should not donate blood or semen or sperm during treatment, during dose interruptions and for 7 days after treatment finishes
- Innovid[®] 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 every time you have heterosexual activity, during treatment, during dose interruptions and for 7 days after the end of treatment even if you have had a vasectomy as seminal fluid may still contain pomalidomide in the absence of spermatozoa.

Each pregnancy prevention method has a different level of effectiveness and mode of action, including in some cases, the prevention of foetal implantation in the womb. Their published success/failure rate is based on using them perfectly.

You, or your female partner, must talk to your doctor, fertility expert or your gynaecologist about which method is most appropriate for you.

- If your partner does become pregnant whilst you are taking or 7 days after you have stopped taking Innovid[®], you should inform your treating doctor immediately and your partner should also consult her doctor immediately.