

Innovid[®] (pomalidomide)

Brochure for Women Patients Not of Childbearing Potential

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.
- 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.
- 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

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 infection

Innovid[®] 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.

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.

Innovid treatment may increase the risk of you developing an infection. People with myeloma are also at a higher risk of infection because of the underlying disease.

Therefore you must tell your doctor immediately if you experience:

- any fever, chills, sore throat, cough, 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 (due to effects on blood cells called 'platelets')
- any chest or leg pain and swelling, especially in your lower leg or calves
- any shortness of breath (from potential chest infection, inflammation of the lung, heart failure or blood clot – please see above).

Damage to nerves in the hands and feet

Innovid[®] 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 Innovid[®]

- 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' Innovid[®]

- 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 had a heart attack, have heart failure, have difficulty breathing, or if you smoke, have high blood pressure, high cholesterol level or are a diabetic
- 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 Imnovid[®] and dexamethasone.

How to store Imnovid[®] safely

- Keep your Imnovid[®] 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.

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 are not able to become pregnant. You will be given a copy of the Patient Card. Your pharmacist will check the Patient Card prior to each dispensing of Innovid[®].

You are considered to be a woman who is not able to become pregnant if you fall into one of the following categories:

- 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 lactation, 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's syndrome or uterine agenesis.