

Innovid[®] (pomalidomide)

Brochure for Women Patients of Childbearing Potential

▼ 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.

Summary

- Innovid[®] 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 Innovid[®] 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 Innovid[®] you should tell your doctor.
- For additional information, please refer to the Patient Leaflet.

Safety Information for all Patients

- You must never take Innovid[®] if:
 - You are pregnant
 - You are breastfeeding
 - You are a woman who is able to become pregnant, even if you are not planning to become pregnant. Women able to become pregnant must use an effective form of contraception for 4 weeks before starting Innovid[®], throughout the duration of the treatment and for 4 weeks after stopping treatment
 - You are allergic to Innovid[®] 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
- Innovid[®] is expected to be harmful to an unborn baby

Side effects

Like all medicines, Innovid[®] 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 Innovid[®] treatment.

Before and during the treatment with Innovid 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 doctor 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 Innovid.

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

Reporting of Adverse Reactions

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You should also report side effects directly via the national reporting system to

ADR Reporting, The Medicines Authority, Post-Licensing Directorate,
Sir Temi Zammit Buildings, Malta Life Sciences Park,
San Gwann SGN 3000, Malta

Website: www.medicinesauthority.gov.mt

e-mail: postlicensing.medicinesauthority@gov.mt

OR

ADR Reporting: www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

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

- If you are pregnant, if you think you may be pregnant or if you are planning to become pregnant, as Innovid[®] 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 Innovid[®] 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 levels 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, 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 Imnovid[®] 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.
- Continue using your effective pregnancy prevention method for a further 4 weeks
- Your doctor will perform a final pregnancy test after 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.
- If Innovid[®] 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 doctor and **MUST NOT** take Innovid[®]. Even if you are not having regular periods or are approaching the menopause you may still be able to become pregnant.
- 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 you **NOT** to become pregnant during treatment with Innovid[®] and for one month after finishing Innovid[®]. You will be given a copy of the Patient Card.
- You should tell your doctor if you are pregnant or think you may be pregnant or are planning to become pregnant, as Innovid[®] is expected to be harmful to an 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 doctor 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 doctor before treatment. These will be repeated every 4 weeks during treatment, during dose interruption and 4 weeks after the treatment has finished (unless it is confirmed that you have had a tubal sterilisation)
- The date and result of the monthly pregnancy test will be documented on the Patient Card. Your pharmacist will check the Patient Card prior to each dispensing of Innovid[®].

- You should start your Innovid[®] treatment as soon as possible after having a negative pregnancy test result.
- If you are able to become pregnant you must use effective methods of contraception for 4 weeks before starting treatment, during treatment (including dose interruptions), and until 4 weeks after stopping treatment. Your doctor will advise you on appropriate methods of contraception as some types of contraception are not recommended with Innovid[®]. It is essential therefore that you discuss this with your doctor.
- Where to get advice on contraception: if you do not currently have effective contraception, your doctor will be able to advise you where you can obtain this.
- If you suspect you are pregnant at any time whilst taking Innovid[®] or in the 4 weeks after stopping treatment, you must stop Innovid[®] immediately and immediately inform your doctor. Your doctor will refer you to a physician specialised or experienced in teratology for evaluation and advice.
- Inform your doctor prescribing the contraception that you are on Innovid[®].
- Inform your doctor prescribing Innovid[®] if you have changed or stopped the method of contraception

Before starting Innovid[®] treatment you should discuss with your doctor 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.

Unless you fall into one of the following categories you must follow the pregnancy prevention 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 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 (bilateral salpingo oophorectomy)
- You have premature ovarian failure, confirmed by a specialist gynaecologist
- You have the XY genotype, Turner's 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 to prevent pregnancy

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

- Use adequate contraception starting 4 weeks before Innovid[®] treatment, during Innovid[®] treatment, during any breaks in Innovid[®] treatment and for 4 weeks after stopping Innovid[®] treatment

or

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

Not all types of contraception are suitable during Innovid[®] treatment. You and your partner should discuss with your doctor suitable forms of contraception that you both find acceptable. If necessary, your hospital team can refer you to a specialist for advice on contraception.

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

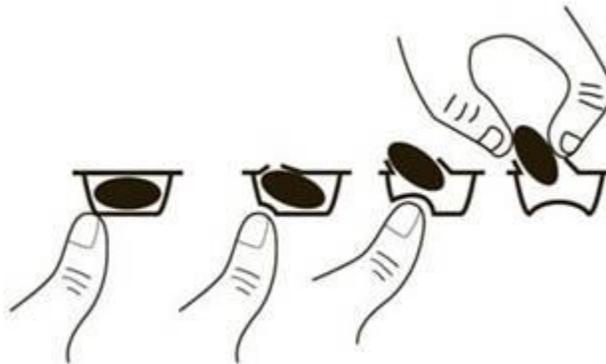
You must talk to your doctor, fertility expert or gynaecologist about which method is most appropriate for you.

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.



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

- 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

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

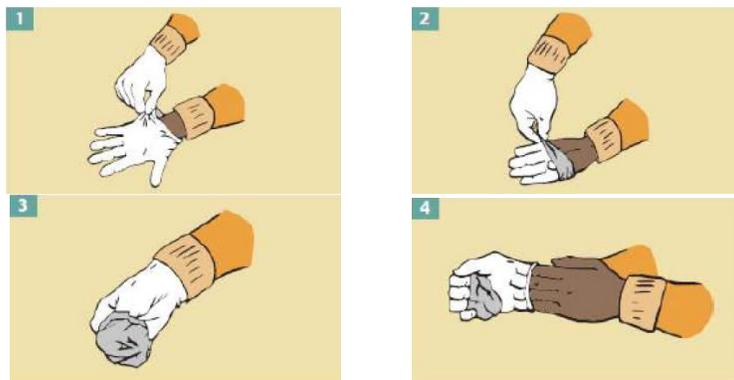
If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protection

- 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 minimize 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 prescribing physician 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 your eye had contact with the powder, 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.