

Innovid[®] (pomalidomide)

Patient Brochures

▼ *This medicinal product is subject to additional monitoring. Healthcare professionals are asked to report any suspected adverse reactions via www.medicinesauthority.gov.mt/adrportal*

The patient brochure provides content for each of the three (3) patient risk categories: women of childbearing potential, women not of childbearing potential, and males

BROCHURE FOR WOMEN PATIENTS 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.
- In order to ensure that an unborn baby is not exposed to pomalidomide, your prescriber will complete a Patient Card_ documenting that you have been informed of the requirement for you NOT to become pregnant throughout the duration of your treatment with pomalidomide and for at least 4 weeks after stopping pomalidomide.
- You should never share pomalidomide 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, during dose interruptions, or for at least 7 days after stopping treatment.
- If you experience any side effects whilst taking pomalidomide you should tell your prescriber or pharmacist.
- For additional information, please refer to the Package Leaflet.
- You must never take pomalidomide if:
 - You are pregnant
 - You are a woman who is able to become pregnant, even if you are not planning to become pregnant, unless all of the conditions of the Pregnancy Prevention Programme are met.

Side effects

Like all medicines, pomalidomide can cause side effects, although not everybody gets them. Some side effects are more common than others and some are more serious than others. Ask your prescriber 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 prescriber. It is important that you talk to your prescriber if you have any side effects during pomalidomide treatment.

Before and during the treatment with pomalidomide you will have regular blood tests. This is because your medicine may cause a fall in the number of cells that help to stop bleeding (platelets).

Your prescriber 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 pomalidomide.

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

Pregnancy Prevention Programme

- If pomalidomide 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 prescriber and **MUST NOT** take pomalidomide. 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 pomalidomide, your prescriber will complete a *Patient Card* documenting that you have been informed of the requirement for you **NOT** to become pregnant throughout the duration of your treatment with pomalidomide and for at least 4 weeks after stopping pomalidomide.
- You should tell your prescriber if you are pregnant or think you may be pregnant or are planning to become pregnant, **as pomalidomide 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 prescriber 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 prescriber before treatment. These will be repeated at least every 4 weeks during treatment, during dose interruption and at least 4 weeks after the treatment has finished (unless it is confirmed that you have had a tubal sterilisation).
- You should start your pomalidomide treatment as soon as possible after having a negative pregnancy test result and having received pomalidomide.
- If you are able to become pregnant you must use at least one effective method of contraception for at least 4 weeks before starting treatment, throughout the duration of your treatment (including dose interruptions), and for at least 4 weeks after stopping treatment. Your prescriber will advise you on appropriate methods of contraception as some types of contraception are not recommended with pomalidomide. It is essential therefore that you discuss this with your prescriber.
- Where to get advice on contraception . Please consult your treating Physician.
- If you suspect you are pregnant at any time whilst taking pomalidomide or in the 4 weeks after stopping treatment, you must stop pomalidomide immediately and immediately inform your prescriber. Your prescriber will refer you to a physician specialised or experienced in teratology for evaluation and advice.
- Inform the prescriber of your contraception that you are on pomalidomide.
- Inform your prescriber of pomalidomide if you have changed or stopped the method of contraception.
- Before starting pomalidomide treatment you should discuss with your prescriber 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 contraceptive 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 breastfeeding, 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 at least 4 weeks before pomalidomide treatment, during pomalidomide treatment, during any breaks in pomalidomide treatment and for at least 4 weeks after stopping pomalidomide treatment.

or

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

Not all types of contraception are suitable during pomalidomide treatment. You and your partner should discuss with your prescriber suitable forms of contraception that you both find acceptable. If necessary, your health care professional can refer you to a specialist for advice on contraception.

BROCHURE FOR WOMEN PATIENTS NOT OF CHILDBEARING POTENTIAL

Summary

- Imnovid® is the trade name for pomalidomide.
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- 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 pomalidomide 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, during dose interruptions, or for at least 7 days after stopping treatment.
- If you experience any side effects whilst taking pomalidomide you should tell your prescriber or pharmacist.
- For additional information, please refer to the Package Leaflet.

Side effects

Like all medicines, pomalidomide can cause side effects, although not everybody gets them. Some side effects are more common than others and some are more serious than others. Ask your prescriber 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 prescriber. It is important that you talk to your prescriber if you have any side effects during pomalidomide treatment.

Before and during the treatment with pomalidomide you will have regular blood tests. This is because your medicine may cause a fall in the number of cells that help to stop bleeding (platelets).

Your prescriber should ask you to have a blood test:

- before treatment

POMANNEXIID2004001
Procedure number EMEA/H/C/002682/II/0036/G
Annex IID update for product handling

- every week for the first 8 weeks of treatment
- at least every month after that for as long as you are taking pomalidomide.

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

Pregnancy Prevention Programme

- In order to ensure that an unborn baby is not exposed to pomalidomide, your prescriber will complete a Patient Card documenting that you are not able to become pregnant.

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 breastfeeding, 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.

BROCHURE FOR MALE PATIENTS

Summary

- Imnovid® is the trade name for pomalidomide.
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- Pomalidomide has been shown to produce birth defects in animals and it is expected to have a similar effect in humans.
- Ask your prescriber to inform you on which are the effective contraceptive methods that your female partner can use.
- You should never share pomalidomide 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, during dose interruptions, or for at least 7 days after stopping treatment.
- If you experience any side effects whilst taking pomalidomide you should tell your prescriber or pharmacist.
- For additional information, please refer to the Package Leaflet.

Side effects

Like all medicines, pomalidomide can cause side effects, although not everybody gets them. Some are more common than others and some are more serious than others. Ask your prescriber 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 prescriber. It is important that you talk to your prescriber if you have any side effects during pomalidomide treatment.

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Your prescriber 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 pomalidomide.

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

Pregnancy Prevention Programme

- In order to ensure that an unborn baby is not exposed to pomalidomide, your prescriber will complete a Patient Card documenting that you have been informed of the requirement for your partner NOT to become pregnant throughout the duration of your treatment with pomalidomide and for at least 7 days after you stop pomalidomide
- Pomalidomide 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 throughout the duration of your treatment, during dose interruptions and at least 7 days after you stop pomalidomide even if you have had a vasectomy.
- If your partner does become pregnant whilst you are taking or within 7 days after you have stopped taking pomalidomide, you should inform your prescriber immediately and your partner should also consult her physician immediately.

You should not donate semen or sperm during treatment, during dose interruptions and for at least 7 days after stopping treatment.

Reporting of suspected adverse reactions

Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system:

POMANNEXIID2004001
Procedure number EMEA/H/C/002682/II/0036/G
Annex IID update for product handling

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

- Please also refer to the Summary of Product Characteristics (SmPC) for further information. <https://www.ema.europa.eu/en/medicines/human/EPAR/innovid-previously-pomalidomide-celgene>

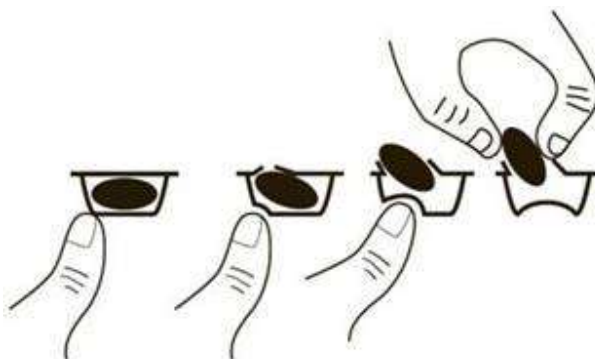
POINTS TO CONSIDER FOR HANDLING THE MEDICINAL PRODUCT: FOR PATIENTS, FAMILY MEMBERS AND CAREGIVERS

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.

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. Refer below for further guidance.



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

- If you are a woman who is pregnant or suspect that you may be pregnant, you should not handle the blister or capsule.
- 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.
- Patients should be advised never to give pomalidomide to another person.

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.

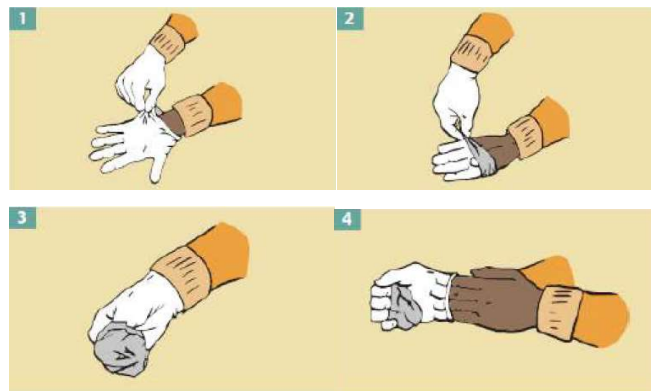
If product is released or spilled, take proper precautions to minimise exposure by using appropriate personal protection

- 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 minimise 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 prescriber 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.