IMNOVID® (POMALIDOMIDE)

RMP- Risk Management Plan

PPP- PREGNANCY PREVENTION PROGRAM

PATIENT BROCHURE

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

1 BROCHURE FOR WOMEN PATIENTS OF CHILDBEARING POTENTIAL

1.1 Summary

- Imnovid® is the trade name for pomalidomide.
- Pomalidomide is structurally related to thalidomide. Thalidomide is a known human teratogenic substance that causes severe life-threatening birth defects. If pomalidomide is taken during pregnancy, a teratogenic effect is expected.
- 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 Registration Form 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 4 weeks 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 Patient 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.

1.2 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 Patient Leaflet. most 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.

1.3 Pregnancy Prevention Programme

- 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.
- In order to ensure that an unborn baby is not exposed to pomalidomide, your prescriber will complete a Patient Registration Form 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.
- 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 sterilization). The pregnancy test must have a minimum sensitivity of 25 mIU/ml. The test must be performed by a healthcare professional, and the result must be negative before pomalidomide treatment can begin or continue.

  Dispensing pomalidomide, , issuing a prescription, pregnancy testing and dispensing should ideally occur on the same day. pregnancy testing should occur no longer than 3 days before issuing the prescription. Dispensing of pomalidomide should occur within 7 days of issuig the prescription.
- If you are able to become pregnant you must use at least one highly effective method AND one additional effective barrier 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.
- 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 specialized 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 menopause may still be able to become pregnant.
- You should start your pomalidomide treatment as soon as possible after having a negative pregnancy test result and having received pomalidomide.
- **Do not take Imnovid®** if you are pregnant or think you may be pregnant or are planning to become pregnant – this is because **Imnovid® is expected to be harmful to an unborn child.**

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 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.

1.4 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 pomalidomide 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.

2 BROCHURE FOR WOMEN PATIENTS NOT OF CHILDBEARING POTENTIAL

2.1 Summary

- Imnovid® is the trade name for pomalidomide.
- Pomalidomide is structurally related to thalidomide. Thalidomide is a known human teratogenic substance that causes severe life-threatening birth defects. If pomalidomide is taken during pregnancy, a teratogenic effect is expected.
- 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 registration Form documenting that you are NOT able to become pregnant.
- 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 4 weeks 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 Patient Leaflet.

2.2 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 Patient Leaflet. most 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.

2.3 Pregnancy Prevention Programme

- In order to ensure that an unborn baby is not exposed to pomalidomide, your prescriber will complete a Patient registration Form 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 syndrome or uterine agenesis.

3 BROCHURE FOR MALE PATIENTS

3.1 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 prescriber to inform you on which are the effective contraceptive methods that your female partner can use.
- In order to ensure that an unborn baby is not exposed to pomalidomide, your prescriber will complete a Patient registration Form 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 4 weeks after you stop 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.
- 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 4 weeks after you stop pomalidomide even if you have had a vasectomy.
- If your partner does become pregnant whilst you are taking pomalidomide or within 4 weeks after you have stopped taking pomalidomide, you should inform your prescriber immediately and your partner should also consult her doctor immediately.
- You should not donate blood or semen or sperm during treatment, during dose interruptions, or for at least 4 weeks 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 Patient Leaflet.

3.2 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 Patient Leaflet. Most 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.

3.3 Pregnancy Prevention Programme

- In order to ensure that an unborn baby is not exposed to pomalidomide, your prescriber will complete a Patient registration Form 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 4 weeks 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 4 weeks after you stop pomalidomide even if you have had a vasectomy.
- If your partner does become pregnant whilst you are taking or within 4 weeks 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 4 weeks after stopping treatment.

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

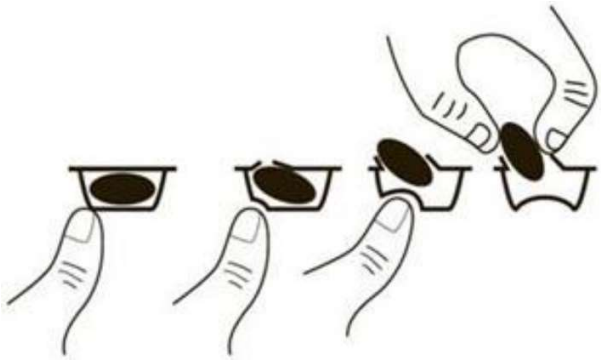
Do not share the medicinal product with anyone else, even if they have similar symptoms. Store them safely so that no-one else can take them by accident and keep them out of the reach of children.

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. The pressure should be located at one site only, which reduces the risk of the capsule deforming or breaking (see figure below).

Healthcare professionals, family members, and caregivers should wear disposable gloves when handling the blister or capsule. Remove gloves carefully to prevent skin exposure. Place in a sealable plastic polyethylene bag. Dispose of any unused medication in accordance with local regulations. 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.



4.1 When Handling the Medicinal Product Use the Following Precautions to Prevent Potential Exposure if You are a Healthcare professional, 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 (ie, blister or capsule).
- Use proper technique when removing gloves to prevent potential skin exposure (see below).
- Place gloves in a sealable plastic polyethylene bag and dispose them according to local requirements.
- Wash hands thoroughly with soap and water after removing gloves.
- Do not give pomalidomide to another person.

4.2 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.

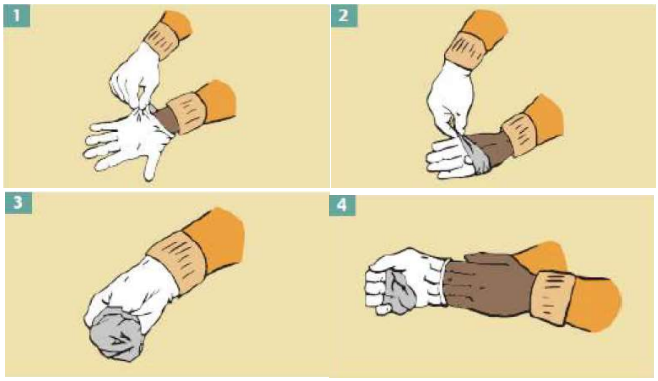
4.3 If Product is Released or Spilled, Take Proper Precautions To Minimize Exposure By Using Appropriate Personal Protection

- If capsules are crushed or broken, dust containing drug substance may be released. Avoid dispersing the powder and avoid breathing on or inhaling 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, then dry it.
- Place all contaminated materials including damp cloth or towel and the gloves into a sealable polyethylene plastic bag. Dispose of it according 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.

4.4 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 drug powder makes contact with one or both of your eyes, remove and discard any contact lenses in use. Then, thoroughly flush eyes with water for at least 15 minutes. If irritation occurs, please contact an ophthalmologist.

4.5 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, being 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.

5 REPORTING OF SIDE EFFECTS

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" that appears on the homepage of the Ministry of Health's website (www.health.gov.il) which links to a portal, or by the following link: https://sideeffects.health.gov.il
and by emailing the Registration Holder's Product Safety and Quality Department at:
drugsafety@neopharmgroup.com
Tel: 03-9373796

6 PERSONAL DATA PRIVACY

Neopharm processes personal data relating to patients receiving this product and to health professionals involved in their therapeutic management, for the purposes of managing and reducing the risk linked to the use of this product as legally required. You may contact us at any time to ask what Personal Data we process about you. If such a request places Neopharm or its affiliates in breach of its obligations under applicable laws, regulations or codes of practice, then Neopharm may not be able to comply with your request. To exercise your rights: privacy@Neopharmgruop.com

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This brochure and its content were reviewed and approved by the Israeli Ministry of Health in Apr/2025.