Lenalidomide Grindeks

(lenalidomide)

Patient brochure

Version 1.0. Date 10.2024

1. INFORMATION FOR WOMEN OF CHILDBEARING POTENTIAL

1.1. Summary

- Lenalidomide Grindeks is the trade name for lenalidomide.
- Lenalidomide is structurally related to thalidomide. Thalidomide is known to cause severe life-threatening birth defects. If used during pregnancy, a teratogenic effect is expected.
- Lenalidomide 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 lenalidomide, your prescriber will complete a *Patient card* and *Risk Awareness Form* documenting that you have been informed of the requirement for you NOT to become pregnant throughout the duration of your treatment with lenalidomide and for at least 4 weeks after stopping lenalidomide.
- You should never share lenalidomide with anyone else.
- You should always return any unused capsules to the pharmacist for safe disposal.
- 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 while taking lenalidomide, talk to your prescribing physician or pharmacist.
- For further information, please read the package leaflet.
- You must never take lenalidomide 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. Adverse reactions

Like all medicines, lenalidomide 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. Most side effects are temporary and can be easily prevented and treated. It is important that you talk to your prescriber if you have any side effects during lenalidomide treatment.

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 lenalidomide 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 ensure 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 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 lenalidomide. It is essential therefore that you discuss this with your prescriber.
- You can get advice on contraception from your family doctor or gynaecologist.
- If you suspect that you may be pregnant, while taking this drug or in the 4 weeks after the end of treatment you must immediately stop taking lenalidomide and inform your treating prescriber. Your prescriber will refer you to a physician specialised or experienced in teratology for evaluation and advice.

2. INFORMATION FOR WOMEN OF NON-CHILDBEARING POTENTIAL

2.1. Summary

- Lenalidomide Grindeks is the trade name for lenalidomide.
- Lenalidomide is structurally related to thalidomide. Thalidomide is a known human teratogenic substance that causes severe life-threatening birth defects. If lenalidomide is taken during pregnancy, a teratogenic effect is expected.
- Lenalidomide 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 lenalidomide, your prescriber will complete a *Patient card* and *Risk Awareness Form* documenting that you are not able to become pregnant.
- You should never share lenalidomide with anyone else.
- You should always return any unused capsules to the pharmacist for safe disposal.
- 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 while taking lenalidomide, talk to your doctor or pharmacist.
- For additional information, please refer to the Package Leaflet.

2.2. Adverse reactions

Like all medicines, lenalidomide 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. Most side effects are temporary and can be easily prevented and treated. It is important that you talk to your prescriber if you have any side effects during lenalidomide treatment.

3. INFORMATION FOR MALE PATIENTS

3.1. Summary

- Lenalidomide Grindeks is the trade name for lenalidomide.
- Lenalidomide is structurally related to thalidomide. Thalidomide is a known human teratogenic substance that causes severe life-threatening birth defects. If lenalidomide is taken during pregnancy, a teratogenic effect is expected.
- Lenalidomide 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 lenalidomide, your prescriber will complete a *Patient Card* and *Risk Awareness Form* documenting that you have been informed of the requirement for your partner NOT to become pregnant throughout the duration of your treatment with lenalidomide and for at least 7 days after you stop lenalidomide.
- You should never share lenalidomide with anyone else.
- You should always return any unused capsules to the pharmacist for safe disposal as soon as possible.
- Lenalidomide passes into human semen. If your partner is pregnant or able to become pregnant, and she doesn't use effective contraception, you must use a condom every time you have sex throughout the duration of your treatment, during dose interruptions and at least 7 days after you stop lenalidomide even if you have had a vasectomy.
- If your female partner becomes pregnant whilst you are taking lenalidomide or within 7 days after you have stopped taking lenalidomide, you should inform your treating physician immediately and your partner should also consult her prescriber immediately.
- You should not donate blood, semen or sperm during treatment, during dose interruptions, or for at least 7 days after stopping treatment.
- For additional information, please refer to the Package Leaflet.

3.2. Adverse reactions

Like all medicines, lenalidomide can cause side effects, although not everybody gets them. Some side effects are more common than others and some are more serious than others.

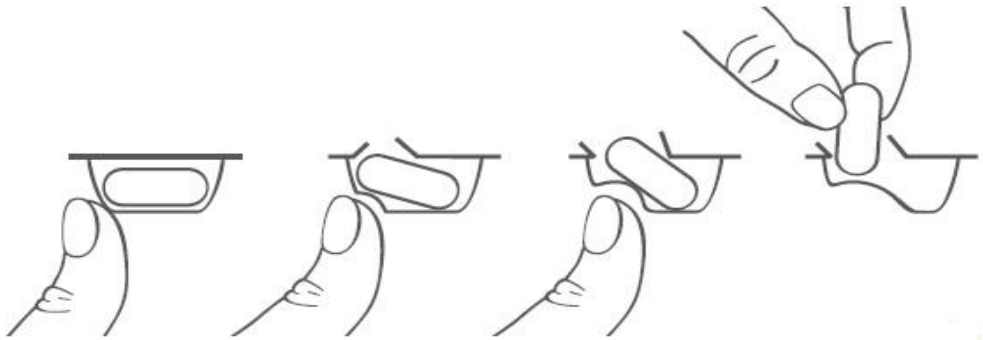
Ask your prescriber or pharmacist if you would like more information and refer to the Package Leaflet. Most side effects are temporary and can be easily prevented and treated. It is important that you talk to your prescriber if you have any side effects during lenalidomide treatment.

4. INSTRUCTIONS FOR HANDLING LENALIDOMIDE: INFORMATION 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 as therefore the pressure is located to one site only which reduces the risk of capsule deformation or breakage (*see below*).



Healthcare professionals and caregivers 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. For further guidance please read the information below.

4.1. 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 the proper technique when removing gloves to prevent potential skin exposure (see below)
- Place gloves in a sealable plastic polyethylene bag and dispose according to local requirements
- Wash hands thoroughly with soap and water after removing gloves.

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.

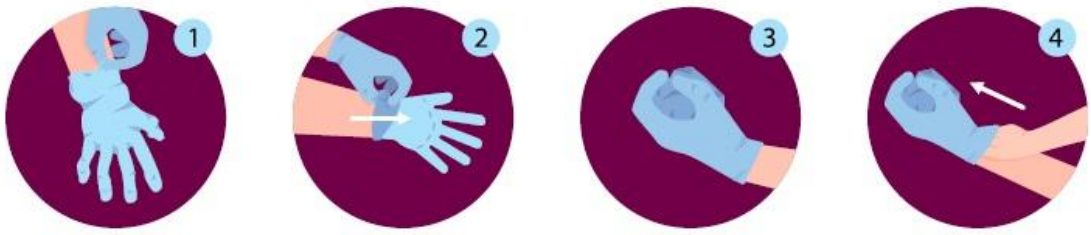
4.3. If product is released or spilled, take proper precautions to minimise exposure by using appropriate personal protection

- 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.

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 the powder gets in contact with your eye, 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.

REPORTING OF SUSPECTED ADVERSE REACTIONS:

Suspected adverse reactions that may occur during treatment with Lenalidomide Grindeks should be reported via adverse drug reactions (ADRs) to Malta Medicines Authority via the ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal.

For further information regarding this medication please contact local representative: EJ Busuttil Ltd.
Phone: 2147184 (service is available 24/7)
Email: safety@ejbusuttil.com
Office Adress:
Busuttil Buildings, Triq l-Ghadam,
Central Business District Zone 1,
Birkirkara CBD1060 MALTA

Adverse events should also be reported to AS GRINDEKS. Krustpils iela 53, Rīga, LV-1057, Latvia
(Marketing Authorisation Holder) at: +371 67083644, E-mail: vigilance@grindeks