Lenalidomide Grindeks

Patient Medication Guide

Warning:

If lenalidomide is taken during pregnancy, there is a risk of severe birth defects in an unborn child. Therefore, it is extremely important that lenalidomide should not be used by a woman who is pregnant or planning to become pregnant.

Lenalidomide can pass into male semen, and it is important to prevent the female partner from being exposed to it.

Your doctor will explain to you the conditions of the Pregnancy Prevention Programme, which must be fulfilled for all patients.

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1. INFORMATION FOR WOMEN OF CHILDBEARING POTENTIAL

Lenalidomide is structurally related to thalidomide. Thalidomide is known to cause severe birth defects in an unborn child. Lenalidomide has been shown to produce birth defects in animals and it is expected to have a similar effect in humans.

- You should start your lenalidomide treatment as soon as possible after having a negative pregnancy test result.
- You should use an effective contraceptive method during lenalidomide treatment and for 4 weeks after completion of treatment.
- You must never take lenalidomide if:
    - You are pregnant.
    - You are a woman who can become pregnant, even if you are not planning to become pregnant, unless all of the conditions of the Pregnancy Prevention Programme are met.
- 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 whilst taking lenalidomide you should tell your prescriber or pharmacist.

PREGNANCY PREVENTION PROGRAMME

- Before starting lenalidomide treatment you should discuss with your prescriber whether 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.
- If you can 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 can 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).
- If you can become pregnant, unless you commit to absolute and continuous abstinence confirmed on a monthly basis, 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 or gynaecologist.

- **DO NOT TAKE LENALIDOMIDE** if you are pregnant, think you may be pregnant or are planning to become pregnant, **as lenalidomide is expected to be harmful to an unborn child.** You should tell your prescriber if you are pregnant or think you may be pregnant or are planning to become pregnant.
- **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.**

ASSESSMENT OF CHILDBEARING POTENTIAL

Unless you fall into one of the following categories you must follow the contraceptive advice in the Pregnancy Prevention Programme outlined in the next 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 breast-feeding, then there is still a chance you could become pregnant)
- Your fallopian tubes and both ovaries or womb have been removed (bilateral salpingo oophorectomy or hysterectomy)
- 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 with a gynaecologist 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.

METHODS OF CONTRACEPTION

The following can be considered to be examples of suitable methods of contraception:

- Implant
- Levonorgestrel-releasing intrauterine system (IUS)
- Medroxyprogesterone acetate depot
- Tubal sterilisation
- Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses

- Ovulation inhibitory progesterone-only pills (i.e. desogestrel)

Inform the prescriber of your contraception that you are on lenalidomide.
Inform your prescriber of lenalidomide if you have changed or stopped the method of contraception.
Not all types of contraception are suitable during lenalidomide treatment. You and your partner should discuss with your prescriber suitable forms of contraception that you both find acceptable.
If necessary, your healthcare professional can refer you to a specialist for advice on contraception.

2. INFORMATION FOR WOMEN OF NON-CHILDBEARING POTENTIAL

Lenalidomide is structurally related to thalidomide. Thalidomide is known to cause severe birth defects in an unborn child. Lenalidomide has been shown to produce birth defects in animals and it is expected to have a similar effect in humans if taken during pregnancy.

- 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 whilst taking lenalidomide you should tell your prescriber or pharmacist.

3. INFORMATION FOR MALE PATIENTS

Lenalidomide is structurally related to thalidomide. Thalidomide is known to cause severe birth defects in an unborn child. Lenalidomide has been shown to produce birth defects in animals and it is expected to have a similar effect in humans if taken during pregnancy.

- 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.
- Ask your prescriber to inform you on which are the effective contraceptive methods that your female partner can use.
- 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.
- You should not donate blood, semen or sperm during treatment, during dose interruptions, or for at least 7 days after stopping treatment.
- 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.

If you experience any side effects whilst taking lenalidomide you should tell your prescriber or pharmacist.

4. LENALIDOMIDE AND OTHER POSSIBLE SIDE EFFECTS

- 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. 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.
- Treatment with lenalidomide is associated with a risk of thromboembolism. Prophylactic antithrombotic medicines may be recommended, especially in patients with additional thrombotic risk factors such as previous history of thromboembolic events, hypertension, hyperlipidaemia or smoking. You should seek medical help if you develop symptoms such as shortness of breath, chest pain, arm or leg swelling.
- Before and during the treatment with lenalidomide 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 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 lenalidomide.

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

5. LENALIDOMIDE TREATMENT

WHAT YOU SHOULD KNOW BEFORE STARTING TREATMENT

Your prescriber will talk to you about what to expect from your treatment and explain the risks and your responsibilities.

If there is anything you do not understand, please ask your prescriber to explain it again.

Before starting treatment, your prescriber will ask you to read and sign a *Lenalidomide Consent Form*, which confirms that while taking lenalidomide:

- You understand the risk of birth defects and the actions you must take to prevent this risk from occurring depending on whether you are a female patient who can become pregnant, a male patient or a female patient who cannot become pregnant;
- If you are able to become pregnant you will follow the necessary requirements to prevent pregnancy;

- You understand the other important safety messages;
- As a male patient, you understand the need to use condoms during treatment (including dose interruptions) and for at least 7 days after stopping lenalidomide if your partner is pregnant or is of childbearing potential and not using effective contraception.

Your prescriber will keep one copy for your medical file and provide one copy to you.

RECEIVING YOUR PRESCRIPTION

- For women of childbearing potential your prescriber will write a prescription for no more than 4 weeks supply.
- For women of non-childbearing potential and male patients your prescriber will write a prescription for no more than 12 weeks supply.
- You must have the medication dispensed within 7 days of the prescription date.

You will need to see your prescriber each time you need a repeat prescription.

HOW TO TAKE YOUR MEDICATION

- Your prescriber will prescribe a dose of lenalidomide suited to you.
- Always take lenalidomide exactly as your prescriber has told you. Check with your prescriber or pharmacist if you are not sure.
- Your prescriber 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 prescriber has prescribed. If in doubt, ask your prescriber or pharmacist for advice. 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 medications.
- Lenalidomide capsules should be swallowed whole, with a glass of water.
- Lenalidomide can be taken at any time of day but it should be taken at approximately the same time each day.
- Lenalidomide can be taken with or without food.
- Do not break, open or overly handle the capsules. If powder from a broken lenalidomide capsule makes contact with the skin, wash the skin immediately and thoroughly with soap and water. If Lenalidomide makes contact with the mucous membranes, they should be thoroughly flushed with water.

6. SAFETY MEASURES DURING TREATMENT

If you take more lenalidomide than you were prescribed, tell your prescriber immediately.

If you forget to take lenalidomide at your regular time take your next capsule as normal the next day. Do not increase the number of capsules you take to make up for not taking lenalidomide the previous day.

Let your prescriber know if you have missed any doses at your next visit.

Other medicines and lenalidomide

Tell your prescriber or nurse if you are taking or have recently taken any other medicines, including medicines bought without a prescription. This is because lenalidomide can affect the way some other medicines work. Also, some other medicines can affect the way lenalidomide works.

If you are seeing a different prescriber or other healthcare professional for treatment (your dentist for example), you should tell them that you are taking lenalidomide and any other medications.

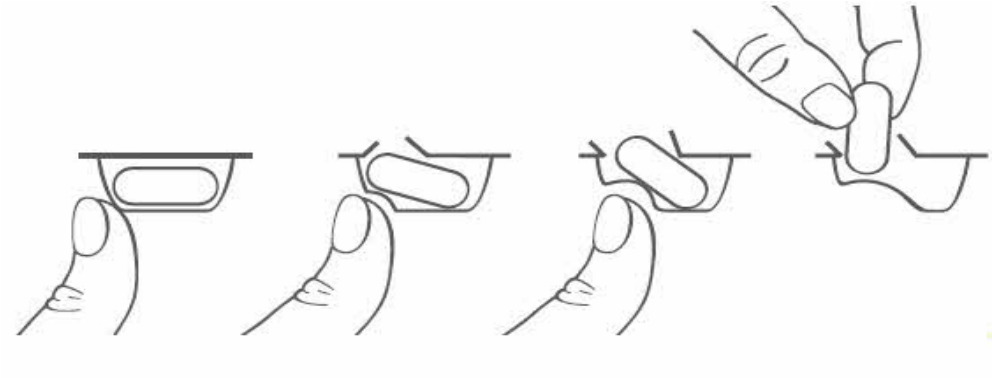
If you have any further questions on the use of this medicine, ask your prescriber or pharmacist.

7. 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*).

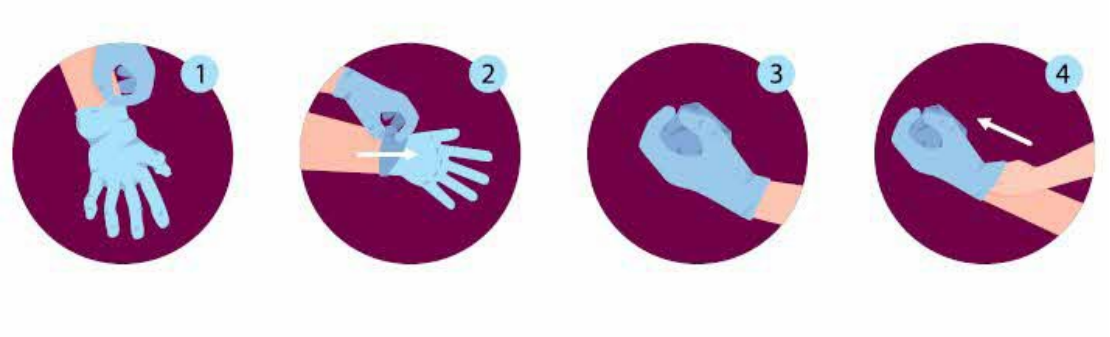


Caregivers should wear disposable gloves when handling the blister or capsule. Gloves should then be removed carefully to prevent skin exposure, placed in a sealable plastic polyethylene bag and disposed of in accordance with local requirements. Hands should then be washed thoroughly with soap and water (*see below the proper technique for removing gloves*).

Women who are pregnant or suspect they may be pregnant should not handle the blister or capsule.

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.



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 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.