Information for Patients

This section contains information about Lenalidomida Generis (lenalidomide) that you should give to your patients.

Lenalidomida Generis

Lenalidomide▼

Pregnancy Prevention Programme

Information for Patients taking Lenalidomida Generis (lenalidomide)

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
Email: postlicensing.medicinesauthority@gov.mt
Or
ADR Reporting: www.medicinesauthority.gov.mt/adrportal

AND/OR

Marketing Authorization Holder: Eugia Pharma (Malta) Ltd. – Vault 14, Level 2, Valletta Waterfront, Floriana, FRN 1914, Malta
Contact: +356 22294000
Email: eupvg@eugiapharma.com

Distributor in the Source Country: Generis Farmacêutica, S.A. – Rua João de Deus, 19, 2700-487, Amadora
Contact: +351 219849300
Email: pharmacovigilance.portugal@aurobindo.com

Local Distributor: Cherubino Limited – DELF Building, Sliema Road, Gzira, GZR 1637, Malta
Contact: +356 21343270
Email: pharmacovigilance@cherubino.com.mt

These documents can also be found at https://medicinesauthority.gov.mt/rmm

This brochure contains information about:

Preventing harm to unborn babies: If Lenalidomide is taken during pregnancy it is expected to cause severe birth defects or death to an unborn baby.

Lenalidomide Pregnancy Prevention Programme: This Programme is designed to ensure that unborn babies are not exposed to Lenalidomide. It will provide you with information about what to expect from your treatment and explain the risks and your responsibilities.

Lenalidomide passes into men's semen and is expected to cause severe birth defects or death to an unborn baby. So, there is a risk if you have unprotected sex with a woman who can become pregnant.

This brochure will help you understand what to do before, during and after taking Lenalidomide.

This brochure will not give you information about multiple myeloma, myelodysplastic syndrome, mantle cell lymphoma or follicular lymphoma you should ask your prescriber if you have any questions.

Warning: Severe life-threatening birth defects. If Lenalidomide is taken during pregnancy it is expected to cause severe birth defects or death to an unborn baby.

Lenalidomide must never be used by women who are pregnant, as just one capsule is expected to cause severe birth defects.

Lenalidomide must never be used by women who are able to become pregnant unless they follow the Lenalidomide Pregnancy Prevention Programme.

For your own health and safety, please read this brochure as well as the Package Leaflet that comes with your medicine, carefully. If you do not understand something, please ask your prescriber for further explanation.

For complete information on all possible side effects please read the Package Leaflet that comes with your Lenalidomide capsules.

This brochure also contains important information about the requirement to avoid blood donation during treatment, the safe handling of Lenalidomide and the safe disposal of unused Lenalidomide capsules.

Contents

Introduction

Lenalidomide works by affecting the body's immune system and directly attacking the cancer. It works in a number of different ways:

- by stopping the cancer cells developing
- by stopping blood vessels growing in the cancer
- by stimulating part of the immune system to attack the cancer cells.

Lenalidomide is licensed in Europe for use in adults for:

- Newly diagnosed multiple myeloma – on its own to treat patients who have had a bone marrow transplant
- Newly diagnosed multiple myeloma – in combination with other medicines to treat patients who cannot have a bone marrow transplant
- Multiple myeloma – in combination with another medicine to treat patients who have had treatment before
- Myelodysplastic syndromes due to low- or intermediate-1-risk – used alone to treat patients when all the following apply:
  - need regular blood transfusions to treat low levels of red blood cells ('transfusion-dependent anemia')
  - have an abnormality of cells in the bone marrow called an 'isolated deletion 5q cytogenetic abnormality'. This means your body does not make enough healthy blood cells
  - other treatments used before are not suitable or do not work well enough.
- Mantle cell lymphoma – used alone to treat patients who have previously been treated with other medicines
- Previously treated follicular lymphoma – taken together with rituximab.

Lenalidomide is structurally related to thalidomide, which is known to cause severe, life-threatening birth defects. Precautions must be taken to avoid exposure to Lenalidomide in an unborn baby.

This brochure contains important information about the Lenalidomide Pregnancy Prevention Programme. You must read the information carefully and before starting treatment you should:

- Understand the risks of Lenalidomide treatment. Please ensure you read the Package Leaflet before you use the medication as it contains information on all the side effects that can occur with Lenalidomide
- Understand the guidelines for taking Lenalidomide safely, including how to prevent pregnancy
- Understand what to expect during your initial and follow-up consultations with your prescriber

- Your prescriber will have explained to you the risks of Lenalidomide treatment and specific instructions that you must follow

- Please make sure that you understand what your prescriber has told you before starting Lenalidomide.

If you don't understand something, please ask your prescriber for further explanation.

Lenalidomide and Birth Defects

All medicines can cause unwanted effects or 'side effects'. An extremely important side effect of Lenalidomide is that if taken during pregnancy, it is expected to cause severe birth defects or death to an unborn baby. The birth defects include shortened arms or legs, malformed hands or feet, eye or ear defects, and internal organ problems. This means Lenalidomide must never be taken by:

- Women who are pregnant
- Women of childbearing potential, unless they follow the Lenalidomide Pregnancy Prevention Programme

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 and refer to the Package Leaflet. Most side effects are temporary and can be easily prevented and 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 Lenalidomide treatment.

▼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.

Reporting of Side Effects

If you get any side effects, talk to your prescriber, pharmacist or nurse. This includes any possible side effects not listed in this brochure. You

can also report side effects directly via www.medicinesauthority.gov.mt/adrportal.

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 interruptions and at least 4 weeks after the treatment has finished (unless it is confirmed that you have had a tubal sterilisation)
- If you are able to 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 the 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. If necessary, your hospital team can refer you to a specialist for advice on contraception
- If you suspect you are pregnant at any time whilst taking Lenalidomide or in the 4 weeks after stopping, you must stop Lenalidomide immediately and immediately inform your prescriber. Your prescriber will refer you to a physician specialised or experienced in teratology for evaluation and advice.

Childbearing Potential Assessment

Female patients will be assessed by their prescriber for childbearing potential, and unless you fall into one of the following categories you must follow the contraceptive advice presented 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, 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.

Contraception Methods for Women of Childbearing Potential

Lenalidomide is expected to be harmful to the unborn child.

- **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 Treatment Initiation 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 as soon as possible
- You should not donate blood during treatment, during dose interruptions, or for at least 7 days after stopping treatment
- For additional information, please refer to 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.

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

Contraception Methods for Males

Lenalidomide is expected to be harmful to the unborn child.

- **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 Treatment Initiation 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
- You should not donate blood, semen or sperm during treatment, during dose interruptions, or for at least 7 days after stopping treatment
- 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 condoms 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 partner does become pregnant whilst you are taking Lenalidomide or within 7 days after you have stopped taking Lenalidomide, you should inform your prescriber immediately and your partner should also consult her prescriber immediately
- For additional information, please refer to the Package Leaflet.

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

Women of Non-childbearing Potential

Lenalidomide is expected to be harmful to the unborn child.

- **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 Treatment Initiation 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 as soon as possible
- You should not donate blood during treatment, during dose interruptions, or for at least 7 days after stopping treatment
- For additional information, please refer to the Package Leaflet.

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

Lenalidomide Treatment

Before Starting Your 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 Treatment Initiation 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.

Safety Measures During Treatment

What to do if you have taken more than the prescribed dose of Lenalidomide:

If you accidentally take too many capsules, contact your prescriber immediately.

What to do if you forget to take your Lenalidomide:

If you forget to take your Lenalidomide and you remember within 12 hours of the missed dose, you can take your Lenalidomide as soon as you remember and continue with the next dose at the normal time. If it is more than 12 hours since the missed dose, leave out that dose altogether and take the next dose at the normal time.

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

Taking other medicines

Please tell your prescriber 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 prescriber or other healthcare professional for treatment (your dentist for example), you should tell them that you are taking Lenalidomide and any other medications.

Receiving Your Prescription

Your prescriber may provide you with a 'Prescription Authorisation Form' that must be provided to the pharmacist, which confirms that all of the Pregnancy Prevention Programme measures have been followed. Your pharmacist will ask to review this documentation prior to dispensing your Lenalidomide.

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

For women of non-childbearing potential and male patients your prescriber will write a prescription for no more than 12 weeks supply.

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

How to Take Your Medication

Your pharmacist can give you help and advice on taking your medications. 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.

- 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

- 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 chew the capsules. If powder from a broken Lenalidomide capsule makes contact with the skin, wash the skin immediately and thoroughly with soap and water.

End of Treatment Requirements

After completing your Lenalidomide treatment, it is important that:

- You return any unused Lenalidomide capsules to your pharmacist
- You do not donate blood for at least 7 days.

Additional advice for women of childbearing potential:

- Continue using your effective method of contraception for at least a further 4 weeks
- Your prescriber will perform a final pregnancy test after at least 4 weeks, unless it is confirmed you have had a tubal sterilisation.

Additional advice for male patients:

- If you have been using an effective method of contraception, you must continue doing so for at least 7 days
- If your female partner has been using an effective method of contraception, she must continue doing so for at least 4 weeks
- Do not donate semen or sperm for at least 7 days.

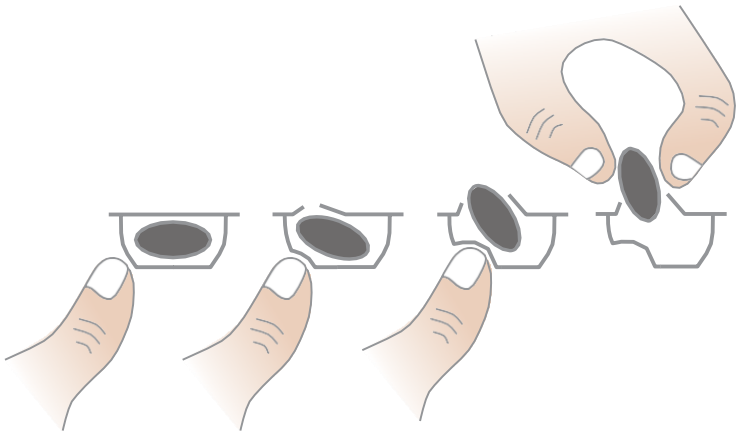
Points to Consider for Handling the Medicinal Product: For Patients, Family Members and Caregivers

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 overleaf 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 the proper technique when removing gloves to prevent potential skin exposure (see over)
- Place gloves in a 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 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 the 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

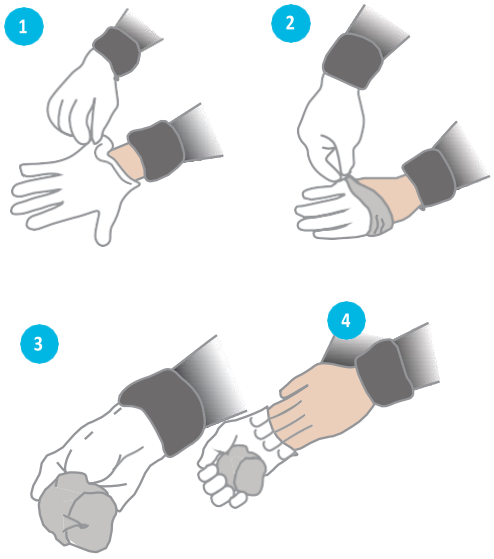
- Place all contaminated materials including damp cloth or towel and the gloves into a sealable polyethylene plastic bag and dispose in accordance to local requirements for medicinal products
- Wash your hands thoroughly with soap and water after removing the gloves
- Please report to the prescriber 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.

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.



Personal Notes

Please use this space to write down any questions for your prescriber for discussion at your next appointment.

Lenalidomida Generis (lenalidomide)

Checklist

Please use this checklist to confirm that you have understood all of the important information regarding your Lenalidomida Generis (lenalidomide) treatment.

All Patients

- ☐ Yes, I have received and understood all the information on the risks of birth defects associated with taking Lenalidomide.
- ☐ Yes, I have received and understood all the information on the risks of other side effects associated with taking Lenalidomide.
- ☐ Yes, I have understood that I must not donate blood during treatment (including dose interruptions), and for at least 7 days after stopping treatment.
- ☐ Yes, I understand that I need to sign the Treatment Initiation Form before starting treatment.

Male Patients

- ☐ Yes, I have understood the need to use condoms during treatment, during dose interruption and for at least 7 days after stopping Lenalidomide, if I have a female partner who is pregnant or is able to get pregnant and not using effective contraception.
- ☐ Yes, I have understood I must not donate semen or sperm during treatment (including during dose interruptions) and for at least 7 days after stopping **Lenalidomide.**

Female Patients who can become pregnant

- ☐ Yes, I will use one effective method of contraception at least for at least 4 weeks before starting Lenalidomide, during therapy (even in the case of dose interruptions) and for at least 4 weeks after I have stopped Lenalidomide treatment.
- ☐ Yes, I understand that I need to have a negative pregnancy test result before starting to take my treatment, and for at least every 4 weeks during treatment and at least 4 weeks after stopping treatment (except in the case of confirmed tubal sterilisation).

Special monitoring

Because Lenalidomide can cause a drop in white blood cell and platelet counts, you will have regular blood tests during treatment. Your prescriber will also monitor how well your kidneys are working. You will have blood tests more frequently in the first few months when you start treatment.

Your prescriber may adjust your dose of Lenalidomide or stop your treatment based on the results of your blood tests and on your general condition. If treatment has to be stopped for any reason, your prescriber will discuss other treatment options with you.

Remember, your pharmacist can give you help and advice on taking your medicines.

Patient Card

Lenalidomida Generis (lenalidomide)

Patient Name, or Initials or Patient unique code/identifier:

Date of Birth or Year of Birth or Age Group: ……

Physician Name: …….

Phone number: ……

Physician to complete each section:

1. Indication:

Multiple Myeloma:

□ ndMM
□ After at least one prior therapy: Line of therapy……
□ Monotherapy for maintenance after autologous stem cell transplantation

Myelodysplastic Syndromes with isolated del5q cytogenetic abnormality: □ Low- or □ intermediate-1 risk

Mantle cell lymphoma relapsed and/or refractory: □

Other: □ Specify……...

2. Status of Patient (tick one)

□ Male
□ Woman of non-childbearing potential
□ Woman of childbearing potential

3. For Woman of Childbearing Potential

Data of Current Visit	Pregnancy Test Date	Pregnancy Test Result	Prescription Date	Physician Signature
__/__/__	__/__/__		__/__/__	
__/__/__	__/__/__		__/__/__	
__/__/__	__/__/__		__/__/__	
__/__/__	__/__/__		__/__/__	
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These documents can also be found at https://medicinesauthority.gov.mt/rmm