Patient information

Lenalidomide Teva® (Lenalidomide)
RMP- Risk Management Plan
PPP- Pregnancy Prevention Program

LENA-PAT-ENG-03

Patient information – Lenalidomide Teva®

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

Your attending physician has registered you to a Risk Management Program / Pregnancy Prevention Program (RMP/PPP).

Warning:

- **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.**

Women:

In order to ensure that an unborn baby is not exposed to Lenalidomide, 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 Lenalidomide and for at least 4 weeks after stopping Lenalidomide.

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.

Men:

Lenalidomide passes into men's semen, so if you are a male patient, there is a risk if you have unprotected sex with a woman who can become pregnant.

The aim of the program is to assist the attending physician to inform you regarding the risks associated with Lenalidomide treatment and to ensure that you are aware of the precautions you need to take before, during and after the treatment.

You must understand and consent to the program conditions to receive the treatment with Lenalidomide Teva.

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1. What is the Medicine Intended for?

Lenalidomide Teva is used to treat adults for the following indications: **Multiple Myeloma (MM), Myelodysplastic Syndromes (MDS), Mantle Cell Lymphoma (MCL), Follicular lymphoma (FL).** Please refer to the patient leaflet for further information about the indications and how to use this medicine.

2. Lenalidomide Teva and Other Possible Adverse Events

Like all medicines, Lenalidomide Teva can cause adverse events , although not everybody gets them. Some adverse events 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 adverse events 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 adverse events during Lenalidomide Teva treatment.

Before and during the treatment with Lenalidomide Teva you will have regular blood tests. This is because your medicine may cause a decrease 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 Teva.

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

If you don't understand something, please ask your prescribing physician or pharmacist for further explanation.

3. Special precautions

Do Not Use the Medicine if:

You are sensitive (allergic) to Lenalidomide or to any of the other ingredients of this medicine (listed in section 6 of patient leaflet).

Blood donation and blood tests

Do not donate blood during the treatment with Lenalidomide, during treatment interruptions and for 4 weeks after treatment discontinuation.

Women:

- Do not use this medicine **if you are pregnant or planning to get pregnant**. Lenalidomide may be dangerous to the fetus, therefore, if you are a woman of childbearing potential – do not use the medicine without using 2 reliable contraceptives.
- After completing use of the medicine, wait at least 4 more weeks before trying to become pregnant.

Men:

Lenalidomide is found in the semen, therefore:

- Do not use this medicine if **you are not capable or not willing to use a condom in each sexual intercourse with a woman of childbearing potential**. Do not donate sperm while taking this medicine, during dose interruptions of the medicine and for at least 4 weeks after discontinuation of this medicine.

4. Women

4.1 Women with no childbearing potential (infertile) criteria

Your prescribing physician will decide if you are a woman with no childbearing potential (infertile) according to the following criteria:

- 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)
- You have premature ovarian failure confirmed by a specialist gynaecologist
- Your fallopian tubes and both ovaries have been removed (bi-lateral salpingo oophorectomy) or your womb has been removed (hysterectomy).
- You have the XY genotype, Turner syndrome, uterine agenesis

4.2 What should you do if you are a Woman of Non-childbearing Potential (infertile)

- In order to ensure that an unborn baby is not exposed to Lenalidomide, your prescriber will complete a program registration form documenting that you are not able to become pregnant.
- You should not donate blood during treatment, during dose interruptions, or for at least 4 weeks after stopping treatment.

4.3 What should you do if you are a woman of childbearing potential:

You must use one highly effective contraceptive method (i.e. an intra-uterine device or implant) AND additional effective barrier method (i.e. condom, diaphragm, cervical cap) before and during the treatment, and for 4 weeks after treatment discontinuation (unless abstinence from sexual activity with a man is the chosen method).
Your attending physician will advise you regarding suitable contraceptives.

You must undergo pregnancy tests under your attending physician's supervision (this includes these women of childbearing potential who confirm absolute and continued abstinence):
The test should be done:

- Before the treatment (once established on contraception for 4 weeks)
- Every 4 weeks during the treatment
- During treatment interruptions
- 4 weeks after the end of treatment

4.4 Pregnancy:

- Do not use this medicine if you are pregnant or planning to get pregnant. Lenalidomide may be dangerous to the fetus, therefore, if you are a woman of childbearing potential, do not use the medicine without using effective contraceptives.
- If you got pregnant during the treatment with Lenalidomide Teva, you must stop the treatment and notify your physician immediately.
- Wait for 4 more weeks after the end of treatment with the medicine before attempting to get pregnant.

5. Men:

Lenalidomide is found in the semen, therefore:

- If your partner is a woman of childbearing potential or is pregnant, you must use a condom during the treatment with Lenalidomide Teva and for 4 weeks after treatment discontinuation, even if you underwent surgical sterilization.
- If your partner becomes pregnant while you are taking Lenalidomide Teva or in the 4 weeks after the end of treatment, tell your physician straight away. Your partner should also tell her physician straight away.
- Do not donate blood, semen or sperm during treatment (including during dose interruptions) and for at least 4 weeks following discontinuation of Lenalidomide.

6. Implementation of the Pregnancy Prevention Program while taking Lenalidomide Teva:

The following conditions must be met to receive the treatment:

☑ The attending physician ordering the treatment is registered to the Risk Management Program.

☑ The pharmacy dispensing the prescription must be registered to the Risk Management Program.

☑ The attending physician must register you to the Risk Management Program (after explaining the program and obtaining your consent to its conditions)

- Patients below the age of 18 will be registered by approval of their legal guardian only.

- If you are a **woman of childbearing potential**, the attending physician must verify that:
  - ☑ 4 weeks before the treatment you are established on one highly effective contraceptive method AND additional effective barrier method (unless absolute and continuous sexual abstinence confirmed on monthly basis).
  - ☑ A negative pregnancy test is available before issuing the prescription (with a minimum sensitivity of 25 mIU/ml). Provide the test results with the prescription. The test results should be from a date no earlier than 3 days prior to issuing the prescription. Ideally, pregnancy testing, issuing a prescription and dispensing should occur on the same day. Dispensing of Lenalidomide Teva to women of childbearing potential should occur within 7 days of the prescription and following a medically supervised negative pregnancy test result. This includes those women of childbearing potential who confirm absolute and continued abstinence.

- If you are a **man** with a partner who is a woman of childbearing potential or is pregnant, the attending physician must verify that:
  - ☑ You use a condom during the treatment with Lenalidomide Teva and for 4 weeks after treatment discontinuation, even if you underwent surgical sterilization.

- A prescription for women of childbearing potential can be for a maximum duration of treatment of **4 weeks**, and prescriptions for all other patients can be for a maximum duration of treatment of **12 weeks**.

For each prescription, compliance with the aforementioned conditions will be checked. **If not all the aforementioned conditions are met, the medicine will not be supplied.**

7. Points to Consider for Handling Lenalidomide Teva: For Patients, Family Members and Caregivers

- Do not break, open or chew the capsules. If powder from a broken capsule makes contact with the skin, wash the skin immediately and thoroughly with soap and water.
- 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 bag and disposed of in accordance with the instructions. 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.**

This medicine has been prescribed for the treatment of your disease. Do not pass it to others. It may harm them even if it seems to you that their medical condition is similar. Return any unused capsules to the pharmacy.

8. Reports on pregnancy during treatment with Lenalidomide Teva should be sent to the following parties:

- **To the Ministry of Health**

By the portal of adverse events reporting at the homepage of the Ministry of Health website **www.health.gov.il**
Or by entering the link: **https://sideeffects.health.gov.il/**

- **To Teva Israel Ltd.:**

Adverse events:

Email: **Safety.israel@teva.co.il**
Phone: **1800-805-005**
Fax: **03-9127870**

Patient registration form for the program should be sent to:

Email: **TevaIL.RMP@teva.co.il**
Fax: **03-9267824**

The above contacts can be also used for reporting adverse events during the treatment with Lenalidomide Teva.

For further information, read the entire patient leaflet carefully before using the medicine. If you have further questions, contact the physician or pharmacist.

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

Information for physicians, the healthcare professionals, patients and pharmacists about the use of personal information – risk management program relating to the administration of Teva's IMiDs[1] drugs.

Teva Pharmaceutical Industries Ltd. (hereinafter: "**Teva**" or "**we**") respects your right to privacy. Your ability to make informed decisions about the use of information belonging to you is important to us. In this document, we specify the information that we collect from you, how we protect it and what uses we make of the information.

Information that we collect

"Personal information" is information that can be attributed to a person or entity, such as a name, address or medical information. The personal information that we collect is collected through the completion of a paper or online registration form for the risk management program (the form is completed by the patient, the treating physician or the pharmacist), which includes, inter alia, name, identity card number (or other identification number), date of birth, membership in an HMO, medical condition and diagnosis, state of pregnancy and/or fertility, the type of treatment and medicines, language preferences, details about parents and/or guardians and/or participation in instructional sessions. The personal information that we collect from physicians, the treatment staff and/or from pharmacists through their completion of the program registration form includes name, institutional affiliation, occupation, license number, telephone number and e-mail address. We also collect any additional personal information that will be provided by patients, physicians, treatment staff and pharmacists in the future within the framework of the risk management plan. We also collect any additional personal information that you provide to us now or in the future. It is your voluntary decision whether or not to provide us with particular information, but we must collect and retain some of the information in order to comply with the statutory and regulatory requirements.

How we protect the information

We employ commercially reasonable and accepted information-security measures to protect the information furnished to us, but there are no electronic transfer or storage methods that are absolutely secure. Therefore, although we try to employ maximum measures to protect your information, we cannot guarantee the absolute security of the information.

[1] Immunomodulatory imide Drugs (IMiDs) by Teva (Lenalidomide Teva®/ Pomalidomide Teva®)

How we use the information

We will not share your information with any other parties without your express consent, apart from in ways explicitly referred to here, unless we will be required to do so pursuant to any law, regulation or court order or for the purpose of cooperating with an investigation by the law enforcement authorities. The main purposes for collecting and saving the information about you are for the participation in risk management programs as is required by law and regulation, for the operation of this program and for the controlled dispensing of the medicine within its framework. We will share the information with the authorized authorities for the purpose of complying with these requirements.

We use external companies as our subcontractors in order to provide us with services relating to the personal information, including in order to participate in a risk management program, and in order to store the personal information on their servers, which will be operated on our behalf. All of the subcontractors that will operate on our behalf will be subject to obligations regarding the use of information and to the obligations by law. We might transfer our databases, which contain your information, if we sell our business or a portion thereof, including while negotiating the sale and including during liquidation but, in such instance, the recipients of the information will undertake to safeguard confidentiality and to act in compliance with the relevant provisions specified in this document.

Right to peruse and amend

You have a right to demand to peruse your information or to update or correct it in particular instances. If you wish to do so, please contact us at [IMPrivacy.Tevail@teva.co.il]. If you have any questions about this privacy policy, if you do not agree to that stated therein or if you wish to contact us about any other matter, please contact us at [IMPrivacy.Tevail@teva.co.il].

I agree that my personal information will be shared and processed as described above and in the respected registration forms. I understand that I am under no legal obligation to provide this information, but without it, I will not be able to receive Teva's IMiDs drugs.

www.teva.co.il

For further information, read the entire patient leaflet carefully before using the medicine.

Patient registration form for the program should be sent to:
Email: TevaIL.RMP@teva.co.il Fax: 03-9267824