Patient Information

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

teva

Patient information – Lenalidomide Teva

Your doctor has registered you to a Risk Management Program / Pregnancy Prevention Program (RMP/PPP).
Lenalidomide Teva was found to be harmful to fetuses in animal studies, therefore it may be dangerous for human fetuses.
The aim of the program is to assist the doctor to inform you regarding the risks associated with Lenalidomide Teva 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.

1. What is the Medicine Intended for?

Lenalidomide Teva is used:

- For treatment of adults with low red blood cell counts, a condition called Myelodysplastic Syndromes (MDS). Lenalidomide Teva 7.5 mg is not indicated for the treatment of MDS.
- For treatment of newly diagnosed multiple myeloma patients who cannot undergo bone marrow transplantation. In combination with dexamethasone, for treatment of adult multiple myeloma patients who have previously received at least one treatment.
- For treatment of adults with refractory and/or recurrent mantle cell lymphoma (MCL).

Lenalidomide Teva can increase the number of red blood cells produced by the body by reducing the number of abnormal cells. The treatment can lead to reduction of the number of required blood units.

2. 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).
- Do not donate blood during the treatment with Lenalidomide Teva, 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 Teva 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.
- Wait for 4 weeks after the end of treatment with the medicine before attempting to get pregnant.
- Do not breastfeed during the treatment with Lenalidomide Teva, during treatment interruptions and for 4 weeks after treatment discontinuation.

Men:

Lenalidomide Teva 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**. If you are sensitive to condoms, your partner must use 2 reliable contraceptives acting by different methods beginning 4 weeks before starting treatment, during the treatment and 4 weeks after the end of treatment.
- Do not donate sperm while taking Lenalidomide Teva, during treatment interruptions and for 4 weeks after discontinuation of treatment with Lenalidomide Teva.
- After treatment discontinuation a condom must be used for 4 additional weeks.

3. Tests and Follow Up for Women of Childbearing Potential:

Women with no childbearing potential (infertile women) are:

- Women who underwent hysterectomy
- Women who underwent bilateral oophorectomy
- Women who are naturally post-menopausal for at least 24 consecutive months*
- Any other case determined by a doctor

***Menopause due to cancer treatment does not exclude the chance of pregnancy.**

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

You must use use two effective contraceptives acting by different methods (such as an oral contraceptive together with a barrier contraceptive, such as a condom or a diaphragm with a spermicide or an intrauterine device or an intrauterine implant) 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 doctor will advise you regarding suitable contraceptives.

If you are a woman of childbearing potential, you must undergo pregnancy tests under your doctor's supervision:

- 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. Pregnancy and Breastfeeding:

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 doctor immediately. Wait for 4 more weeks after the end of treatment with the medicine before attempting to get pregnant.

Do not breastfeed during the treatment with Lenalidomide Teva, during treatment interruptions and for 4 weeks after discontinuation of treatment with Lenalidomide Teva.

5. Men:

Lenalidomide Teva 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 the man is sensitive to latex or polyurethane, the partner must use at least one most effective contraceptive or two effective contraceptives acting by different methods. The partner must use contraceptives for at least 4 weeks preceding the beginning of sexual intercourse with the patient, during the treatment with Lenalidomide Teva and for 4 more weeks after treatment discontinuation

If your partner got pregnant during your treatment with Lenalidomide Teva, notify her doctor and your doctor immediately.
Do not donate sperm during the treatment, during treatment interruptions and for 4 weeks after treatment discontinuation.

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

The following conditions must be met to receive the treatment:

- The doctor ordering the treatment is registered in the Risk Management Program
- The pharmacy dispensing the prescription must be registered in the Risk Management Program
- The doctor 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 doctor must verify that:
  - 4 weeks before the treatment you are established on contraception.
  - A negative pregnancy test is available before issuing the prescription (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).
- A prescription will be given for a period of 4 weeks only.

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. 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 side effects 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 Pharmaceutical Industries Ltd.:**

By Email: Safety.israel@teva.co.il

By Phone: 03-6864000

By Fax: 03-9127870

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 doctor or pharmacist.

This brochure and its content were reviewed and approved by the Ministry of Health in November 2020

Information for physicians, the treatment staff, patients and pharmacists about the use of personal information – risk management program relating to the administration of the drug Lenalidomide

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.

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 [IL_Privacy.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 [IL_Privacy.Tevail@teva.co.il]

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