Patient Brochure Lenalidomide-Teva (Lenalidomide)

PPP- Pregnancy Prevention Program

PATIENT INFORMATION

Your doctor has registered you to the Lenalidomide-Teva Pregnancy Prevention Program (PPP).

Lenalidomide-Teva is a known teratogen and can cause severe life-threatening human birth defects. If it is taken during pregnancy, it may cause birth defects or death to an unborn baby.

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.

What is the medicine intended for?

Lenalidomide-Teva is used in adults for multiple myeloma.

Multiple myeloma
Multiple myeloma is a type of cancer which affects a certain kind of white blood cell, called the plasma cell. These cells collect in the bone marrow and divide, becoming out of control. This can damage the bones and kidneys.

Multiple myeloma generally cannot be cured. However, the signs and symptoms can be greatly reduced or disappear for a period of time. This is called a 'response'.

Newly diagnosed multiple myeloma – in patients who have had a bone marrow transplant

Lenalidomide-Teva is used on its own as maintenance therapy after patients have recovered enough following a bone marrow transplant.

Newly diagnosed multiple myeloma – in patients who cannot have a bone marrow transplant

Lenalidomide-Teva is taken with other medicine:
- an anti-inflammatory medicine called 'dexamethasone'.

Please refer to the following sections of this brochure for important information about how to avoid the risk of foetal exposure for patients receiving Lenalidomide-Teva.

- For women who are able to become pregnant, please refer to sections 1 & 4.
- For women who are NOT able to become pregnant, please refer to sections 2 & 4.
- For male, please refer to sections 3 & 4.

Contents

Section 1: Requirements for women who are able to become pregnant*

What should you do if you are able to become pregnant:

Use effective methods of contraception:

- For at least 4 weeks before starting Lenalidomide-Teva treatment
- While taking Lenalidomide-Teva
- During any interruption in Lenalidomide-Teva treatment
- At least until 4 weeks following the conclusion of your Lenalidomide-Teva treatment

Before starting treatment:

- You must sign the Patient Registration Form, agreeing not to become pregnant while taking Lenalidomide-Teva and following 4 weeks after the conclusion of your Lenalidomide-Teva treatment.
- You must use two effective methods of birth control (contraception)† for at least 4 weeks before treatment, during treatment, and until at least 4 weeks after Lenalidomide-Teva treatment.
- You must have one negative medically supervised pregnancy test confirmed by your doctor.
  - Either at the time of consultation, or in the 3 days prior to the visit to the doctor.
  - The pregnancy test must be medically supervised and not a pregnancy test from a pharmacy.

* Includes women who are menstruating, amenorrhoeic due to previous medical treatment, <50 years of age and/or peri-menopausal; women who have not been in natural menopause for ≥12 consecutive months.

† Suitable methods of contraception include implant, levonorgestrel releasing intrauterine system, , medroxyprogesterone acetate depot, tubal sterilisation, sexual intercourse with a vasectomised male partner only (vasectomy must be confirmed by two negative semen analyses), and ovulation inhibitory progesterone-only pill (i.e. desogestrel).

Combined oral contraceptives are not recommended. Please ask your doctor which birth control method you should use.

During treatment (including treatment interruption):

- You must ensure that you receive Lenalidomide-Teva within 7 days after being prescribed otherwise you will need a new prescription.
- You should start Lenalidomide-Teva treatment as soon as possible after having a negative pregnancy test result.
- To prevent a pregnancy you must either:
  - continue to use two effective methods of birth control (contraception), or
  - agree you will NOT engage in sexual activity with a male partner.
- You must also undergo regular medically supervised pregnancy tests, regardless of whether continuous abstinence is practised
  - at least every 4 weeks during treatment, and
  - the pregnancy tests should be performed on the day of the visit to the doctor or in the 3 days prior to the visit.
- You must not breastfeed or donate blood.
- Never share your Lenalidomide-Teva capsules.

Note: If you miss a period, experience any abnormality in menstrual bleeding, become pregnant or suspect pregnancy

- **Stop taking your Lenalidomide-Teva immediately, tell your doctor straight away and have a pregnancy test.**

For 4 weeks after treatment:

- You must continue to use two effective methods of birth control (contraception).
- You must continue the medically supervised pregnancy tests every 4 weeks, ensuring that a pregnancy test is conducted at least 4 weeks after stopping treatment.
- You must not breastfeed or donate blood.

Note: If you miss a period, experience any abnormality in menstrual bleeding, become pregnant or suspect pregnancy

- Tell your doctor immediately and have a pregnancy test.

Section 2: Requirements for women who are NOT able to become pregnant

Women who are not able to become pregnant include:

- Women who underwent hysterectomy.
- Women who underwent bilateral salpingo-oophorectomy.
- Women who are at least 50 years old and have been naturally postmenopausal for at least 12 months. **Absence of menstruation due to cancer treatment or during breastfeeding does not exclude the chance of pregnancy.**
- Any other case determined by a doctor.

Before starting treatment:

- You must sign a Patient Registration Form, indicating that you are not able to become pregnant.

  This means that you
  - are at least 50 years old and have been naturally postmenopausal for at least 12 months or
  - have premature ovarian failure confirmed by a specialist gynaecologist or
  - have had your uterus removed (hysterectomy) or
  - have had both fallopian tubes and ovaries removed or
  - have XY genotype or
  - have Turner Syndrome or
  - have uterine agenesis.

During treatment:

- You must not donate blood.
- Never share your Lenalidomide-Teva capsules.

For 4 weeks after treatment:

- You must not donate blood.

Section 3: Requirements for men

Before starting treatment:

- Lenalidomide, when taken, may become present in semen. You must therefore sign a Patient Registration Form agreeing to comply with the requirements for your partner not to become pregnant during treatment with Lenalidomide-Teva and for at least 4 weeks after the conclusion of Lenalidomide-Teva treatment.

During treatment:

- You must use a condom EVERY TIME you have sexual intercourse with a woman who either is or can become pregnant (even if you have had a successful vasectomy).
- You must tell your doctor immediately if you think for any reason that your partner may be pregnant.
- You must not donate blood or sperm.
- Never share your Lenalidomide-Teva capsules.

For 4 weeks after treatment:

- You must continue to use a condom EVERY TIME you have sexual intercourse with a woman who either is or can become pregnant (even if you have had a successful vasectomy).
- You must tell your doctor if you think for any reason that your partner may be pregnant.
- You must not donate blood or sperm.

Note: You must contact your doctor or hospital team immediately if you suspect that your partner is pregnant.

Section 4: Information for all patients

How and when to take Lenalidomide-Teva

- Lenalidomide-Teva must be given to you by healthcare professionals with experience in treating multiple myeloma.
- You should swallow Lenalidomide-Teva capsules whole, preferably with water.
- Do not break, open or chew the capsules. Lenalidomide-Teva capsules can be taken either with or without food.
- You should take Lenalidomide-Teva at about the same time on the scheduled days.
- Always take Lenalidomide-Teva exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

What to do if you forget to take your Lenalidomide-Teva

If you forget to take Lenalidomide-Teva at your regular time and

- Less than 12 hours have passed: take your capsule immediately.
- More than 12 hours have passed: do not take your capsule. Take your next capsule at the usual time the next day.

If you have any further questions on the use of this medicine, please reach out to your doctor or pharmacist.

How to store Lenalidomide-Teva safely

- Store below 30°C.
- Keep this medicine out of the sight and reach of children.
- Do not use Lenalidomide-Teva after the expiry date, which is stated on the blister after "EXP". The expiry date refers to the last day of that month.
- Do not use this medicine if you notice any damage or signs of tampering to the pack.
- Do not throw away any medicines via wastewater or household waste.
- All unused Lenalidomide-Teva capsules should be returned to the pharmacist. These measures will help protect the environment.

Other information

- Do not donate blood during treatment and for at least 4 weeks after the end of treatment.
- Refer to the Lenalidomide-Teva Patient Information Leaflet side effects.
- Speak with your doctor or pharmacist for more information about Lenalidomide-Teva.
- Contact your doctor or hospital team urgently if you suspect that you or your partner are pregnant.

Receiving your prescription

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

For women who can become pregnant, 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 who cannot become pregnant 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.

Reports on adverse events and pregnancy during treatment with Lenalidomide-Teva to be sent to:

Teva Pharmaceutical Investments Singapore Pte. Ltd.
By Email: Safety.Singapore@teva.sg

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Information for physicians, the treatment staff, patients and pharmacists about the use of personal information – Pregnancy Prevention Program relating to the administration of the drug Lenalidomide-Teva

Teva Pharmaceutical Investments Singapore Pte. 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 Pregnancy Prevention 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 any private or public health insurance plan or cooperative, 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 may 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 Pregnancy Prevention Program. We may also collect any additional personal information that you may provide to us now or in the future. It is your voluntary decision whether or not to provide us with particular information, and in doing so, you have consented to our collection of your personal information for any one or more of the above-mentioned purposes, including the collection and retention of 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 Pregnancy Prevention Program 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 may also use or share your personal information in order to provide or carry out services that may be ancillary to but necessary for your participation in the Pregnancy Prevention Program or any other services that you may have requested from us.

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 the Pregnancy Prevention 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 and to afford your personal data a standard of care and protection that is at least comparable to that required under the Personal Data Protection Act 2012.

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, or 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]. While we will try our best to accommodate your request, we reserve the right to impose certain restrictions and requirements on such access requests, if allowed or required by applicable laws, such as, without limitation, where providing access could reasonably be expected to cause immediate or grave harm to the safety or to the physical or mental health of the individual who made the request.

Where you have withdrawn your consent, we will only retain such minimum necessary information pursuant to the applicable laws or any legal requirements. We may also decide for statistical analysis reasons or for business improvement purposes to keep track of your activity data on an aggregated or anonymous basis. Please note that we may not be able to provide the requested services or fulfil the purposes for which your personal information had been collected if you withdraw your consent.

Retention of personal data
We will retain your personal information for as long as the purposes for which you had provided such information to us requires it or as required by applicable law. We may also retain your personal information in a form that can no longer be associated with a particular individual (i.e., anonymised form), once said personal information is no longer required for the purpose for which it was collected, and retention is no longer necessary for legal or business purposes.

Modifications to this policy
For Healthcare Providers:
We reserve the right to change this privacy policy for any reason at any time without prior notice to you other than by either posting such revisions in a manner accessible to you, or and on our website or via email notification. Such changes will be effective upon notice being given to you in either of the above-mentioned ways. The provisions contained herein supersede all previous notices or policies regarding our privacy practices.

For Patients:
We reserve the right to change this privacy policy for any reason at any time without notice to you other than by making such revisions accessible to you via your Healthcare Provider. If the revisions or changes to this privacy policy result in any collection, use or disclosure of your personal information in a manner not contemplated by this privacy policy, we may seek your consent again.

For more information, please refer to the Patient Information Leaflet.

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