Dr.Reddy's

Reddy-Lenalidomide RMP Program: Patient Guide

About the Reddy-Lenalidomide RMP Program:
Lenalidomide can cause serious harm to an unborn baby and must not be given to a female who can become pregnant, unless it is through the Reddy-Lenalidomide RMP program.
LENANGIO (Lenalidomide) is approved for marketing only under a controlled distribution program approved by Health Sciences Authority. This is a requirement by Health Sciences Authority for LENANGIO (Lenalidomide) to prevent exposure to Lenalidomide in unborn babies, as well as to inform prescribers and patients on the serious risks and safe-use conditions for LENANGIO (Lenalidomide). Only registered prescribers and their institutions in the Reddy-Lenalidomide RMP program can prescribe or dispense this medication. In order to receive LENANGIO (Lenalidomide), all patients must be enrolled in the Reddy- Lenalidomide RMP program and agree to comply with the requirements of the program.

Patient Risk Category
Before prescribing LENANGIO (Lenalidomide), your prescriber will determine your risk category and counsel you accordingly:

1. **Females of Child-Bearing Potential**
   - Females who do not qualify for the females not of child-bearing potential category
2. **Females Not of Child-Bearing Potential**
   Females who met at least one of the following criteria:
   - ≥ 50 years and have been in natural menopause for ≥ 1 year (excluding amenorrhea from cancer therapy or during breastfeeding)
   - Premature ovarian failure confirmed by a specialist gynaecologist
   - Previous bilateral salpingo-oophorectomy (have had both fallopian tubes and ovaries removed), or hysterectomy (have had your uterus removed)
   - XY genotype, Turner syndrome, uterine agenesis
3. **Male Patients**

Safety Measures
For all patients

- This medication is strictly for you. Do not share it with anyone even if they have similar symptoms like yours because it may harm them or cause birth defects
- LENANGIO (Lenalidomide) must be kept out of the reach of children and pets
- 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.
- Do not donate blood while you are taking Lenalidomide, during breaks (dose interruptions), and for at least 4 weeks after stopping Lenalidomide
- Unused LENANGIO (Lenalidomide) capsules should be returned for disposal to the institution that dispensed LENANGIO (Lenalidomide) to you

For Females of child-bearing potential:

1. Must use 2 different forms of effective birth control at the same time every time you have sex with a man starting at least 4 weeks before therapy, during dose interruptions, during therapy and for at least 4 weeks following discontinuation of the medication, or completely abstain from heterosexual contact during these times.
2. Must have pregnancy tests performed by your doctor on the same day of the visit to the doctor before being prescribed the medication for the first time, then at least every 4 weeks during the treatment. The pregnancy tests during the treatment should be performed on the day of the visit to the doctor or in the 3 days prior to the visit. A pregnancy test should also be conducted at least 4 weeks after stopping treatment.
   Pregnancy tests are required even if you have not had your menstrual period due to treatment of your disease
   Pregnancy tests must be blood tests, urine tests are not acceptable
3. The institution must dispense your medication within 7 days of your prescription. If the medication is not dispensed to you within 7 days, another prescription will be required.
   Stop taking Lenalidomide immediately and contact your prescriber if you become pregnant, miss a menstrual period or experience unusual bleeding, stop using contraception, or think for any reason you may be pregnant.

For Males

1. Lenalidomide passes into human semen.
2. If your female partner is pregnant or able to become pregnant, and she does not use effective methods of contraception, you must use condoms during treatment and at least 4 weeks after the end of treatment, even if you have had a vasectomy.
3. If your partner becomes pregnant whilst you are taking Lenalidomide, you should inform your doctor immediately. It is recommended that your partner seeks medical advice.

- Take LENANGIO (Lenalidomide) exactly as prescribed and follow all requirements of the Reddy- Lenalidomide RMP program
- Talk to your healthcare provider if you experience any problems while taking LENANGIO (Lenalidomide)

How to Receive Prescriptions for LENANGIO (Lenalidomide)
Initial Prescription:

1. Enroll in the Reddy-Lenalidomide RMP Program
   - You and your healthcare provider will complete and submit the Informed Consent Form.
2. Receive Counseling
   - Your healthcare provider will counsel you on why and how you and your partner should prevent pregnancy to avoid the risk of birth defects or fetal death
   - Your healthcare provider will also inform you not to share the drug, not to donate blood, and about contraception requirements applicable to you.
   - This Patient Guide will be provided to you by your healthcare provider.
3. Get Pregnancy tests (Females of child-bearing potential only)
   - If you can get pregnant, you must take an initial pregnancy test on the same day of receiving a LENANGIO (Lenalidomide) prescription
4. Prescription
   - Your healthcare provider will write your prescription
5. Receive LENANGIO (Lenalidomide)
   - LENANGIO (Lenalidomide) will be dispensed to you by the same institution where you were prescribed the medication

Following Prescriptions:

1. For each of your following prescriptions, you will need to follow a similar process
2. Receive Counseling (all patients)
   - Your healthcare provider will counsel you on why and how you and your partner should prevent pregnancy to avoid the risk of birth defects or fetal death
3. Get a pregnancy test (Females of child-bearing potential only)
   - At least every 4 weeks

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- The pregnancy tests should be performed on the day of the visit to the doctor or in the 3 days prior to the visit.

4. Prescription
   - Your healthcare provider will write your prescription
5. Receive LENANGIO (Lenalidomide)
   - LENANGIO (Lenalidomide) will be dispensed to you by the same institution where you were prescribed the medication

Restarting therapy after discontinuation:

1. You must be re-enrolled in the Reddy-Lenalidomide RMP program if LENANGIO (Lenalidomide) is required and previous therapy has been discontinued. The program requirements must be met every time you start a new course of treatment following discontinuation, including the negative pregnancy test (for females of child-bearing potential) before starting therapy

Important Information for Females of Child-Bearing Potential

Before taking LENANGIO (Lenalidomide)

- You must fill and sign the Informed Consent Form that says you understand that Lenalidomide should not be used during pregnancy as it may cause serious birth defects. You must agree that you will not take Lenalidomide if you are pregnant, become pregnant during treatment or during breastfeeding
- If there is any chance that you can get pregnant, you must agree to use at the same time 2 effective methods of birth control every time you have sex with a male starting at least 4 weeks before taking Lenalidomide, during treatment, during dose interruptions and at least 4 weeks after stopping treatment, or completely abstain from heterosexual sexual contact.
- Your healthcare provider must give you a pregnancy test on the same day of the visit before you receive your first prescription for LENANGIO (Lenalidomide). If you are pregnant, you cannot take Lenalidomide.
- You will have pregnancy tests before starting Lenalidomide and while taking Lenalidomide, even if you agree not to have sex with males
- Before starting LENANGIO (Lenalidomide), you must fill out an Informed Consent Form with your healthcare provider.
- Your healthcare provider will talk with you about your birth control options
  Talk to your healthcare provider about acceptable birth control methods. Use **2 methods** of birth control at the same time
- Remember: You must use at the same time 2 effective methods of birth control every time you have sex with a male.
- Talk to your healthcare provider to make sure that other medicines or dietary supplements you are taking do not interfere with your birth control methods
- Remember, not having sex is the only birth control method that is **100% effective**

While taking LENANGIO (Lenalidomide)

- If you are able to get pregnant, you must continue (including during breaks [dose interruptions]) to use at the same time 2 effective methods of birth control every time you have sex with a male or commit to abstaining from heterosexual sexual contact
- You must talk to your healthcare provider before changing any birth control methods you have already agreed to use
- You will have a pregnancy test performed by your healthcare provider at least every 4 weeks.
- If you get pregnant during your treatment with lenalidomide, you must immediately stop taking Lenalidomide and contact your healthcare provider immediately to discuss your next options. If you do not have an obstetrician, your healthcare provider will refer you to one for care and counseling.
- You must not breastfeed if you are taking Lenalidomide

After stopping LENANGIO (Lenalidomide)

- You must continue to use 2 effective methods of birth control at the same time whenever you have sex with a male:
  1. For at least 4 weeks after stopping Lenalidomide, or
  2. Do not have any sex with a male for at least 4 weeks after stopping Lenalidomide
- Do not donate blood for at least 4 weeks after stopping Lenalidomide

Important Information for Females Not of Child-Bearing Potential

Before taking LENANGIO (Lenalidomide)

- You must sign the Informed Consent Form and confirm that you are not able to get pregnant because:
  1. You are ≥ 50 years and have been in natural menopause for ≥ 1 year (excluding amenorrhea following cancer therapy, breastfeeding, a hysterectomy, and/or bilateral oophorectomy)

  or
  2. You are diagnosed with XY genotype, Turner's syndrome, uterine agenesis, or premature ovarian failure confirmed by a gynecologist.

While taking LENANGIO (Lenalidomide)

- Do not donate blood while you are taking Lenalidomide or during breaks (dose interruptions)

After Stopping LENANGIO (Lenalidomide)

- Do not donate blood for at least 4 weeks after stopping Lenalidomide

Important Information for Males

Before taking LENANGIO (Lenalidomide)

- You must sign the Informed Consent Form. You must agree that while taking Lenalidomide, you will use a condom **every time** you have sex with a female who is pregnant or who is able to get pregnant.
- You must contact your doctor immediately if you think your female partner becomes pregnant while you are taking -Lenalidomide

While taking LENANGIO (Lenalidomide)

- You must use a condom **every time** (including during breaks [dose interruptions]) you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
- **Remember, not having sex is the only birth control method that is 100% effective**
- You must tell your healthcare provider right away if you think for any reason that your partner is or may be pregnant.

After stopping LENANGIO (Lenalidomide)

- For at least 4 weeks after receiving your last dose of Lenalidomide, you must use a condom **every time** you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)

Adverse Event Reporting

If you experience side effects while taking LENANGIO (Lenalidomide), you must tell your healthcare provider.

This document has been approved by HSA as of 24 Aug 2021.

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