Reddy-Lenalidomide RMP Program: Prescriber & Pharmacy Guide

LENANGIO (Lenalidomide) Indication:
Lenalidomide as monotherapy is indicated for the maintenance treatment of adult patients with newly diagnosed multiple myeloma who have undergone autologous stem cell transplantation.

Lenalidomide in combination with dexamethasone is indicated for the treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant.

Lenalidomide in combination with dexamethasone is indicated for the treatment of multiple myeloma in adult patients who have received at least one prior therapy.

Due to its structural similarity to thalidomide, a known teratogen, Lenalidomide is contraindicated in pregnancy. Females of reproductive potential may be treated with Lenalidomide if they take adequate precautions to avoid pregnancy.

LENANGIO (Lenalidomide) Contraindications

- LENANGIO (Lenalidomide) is contraindicated in patients who are hypersensitive to the active substance or to any of the excipients.
- Lenalidomide is contraindicated in pregnant women.
- Lenalidomide is contraindicated in women of childbearing potential unless all of the conditions of the Pregnancy Prevention Programme are met.

Goals of the Reddy-Lenalidomide RMP Program:

1) Prevent pregnancy and risk of embryo-fetal exposure to Lenalidomide
2) Inform prescribers, pharmacists, and patients on the serious risks and safe-use of Lenalidomide

About the Reddy-Lenalidomide RMP Program:
LENANGIO (Lenalidomide) is approved for marketing only under a controlled distribution program approved by Health Sciences Authority. This program is called the Reddy-Lenalidomide RMP Program. This is a requirement by Health Sciences Authority for LENANGIO (Lenalidomide) to ensure that the benefits of the drug outweigh the risk of embryo-fetal exposure to Lenalidomide, as well as to inform prescribers, pharmacists and patients on the serious risks and safe-use conditions for Lenalidomide . To avoid embryo- fetal toxicity, only registered prescribers and pharmacies 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.
Information about the Reddy-Lenalidomide RMP Program can be obtained by calling the Reddy- Lenalidomide RMP Singapore Contact Centre at **+65 6275 7757**, or through email at **customerservice@zyfas.com**

Key Points for the Prescriber

- To enroll in the Reddy-Lenalidomide RMP program and prescribe LENANGIO (Lenalidomide), all prescribers must complete and return the Prescriber Registration Form to receive a unique prescriber ID number. The prescriber ID number will be sent to the prescriber via email during office hours.
- The prescriber must counsel patient on benefits and risks of Lenalidomide, and on the safe use of this drug at every visit.
- The prescriber must provide the patient with patient-education material (including the most updated Patient Guide of the Reddy-Lenalidomide RMP program).
- The prescriber determines the patient risk category and completes an Informed Consent Form in order for each patient to receive a unique patient ID number. The prescriber should keep the form for their records and send a copy of the form via email to **customerservice@zyfas.com.** The patient ID number will be sent to the prescriber via email during office hours.
- Prescriber must conduct and monitor pregnancy testing to verify negative pregnancy tests for all female patients of child-bearing potential with new and subsequent prescriptions. They must report any pregnancies in relation to patients using LENANGIO (Lenalidomide) therapy immediately to the Reddy-Lenalidomide RMP Singapore Contact Centre.
- Once the patient has been registered and counselled the prescriber should, as part of the prescription processing:
  - For female patients of child-bearing potential: Request medically supervised pregnancy tests and confirm negative status
  - For all patients: Write and sign prescription and ensure it includes prescriber ID, Patient ID, days' supply that does not exceed maximum permitted for the patient risk category
  - Send prescription to the pharmacy in a timely manner
- The prescriber writes no more than a 4-week (28-day) supply for females of child-bearing potential (12-weeks (84 days) for all other patients - males, females not of child-bearing potential). No automatic refills or telephone prescriptions allowed.
- Include your unique prescriber ID number and your patient's unique ID number, on every prescription written for LENANGIO (Lenalidomide).

Key Points for the Pharmacy

- To enroll in the Reddy-Lenalidomide RMP program and dispense LENANGIO (Lenalidomide), all pharmacies must complete and return the Pharmacy Registration Form to receive a unique pharmacy ID number. The pharmacy ID number will be sent to the pharmacy via email during office hours.
- Every pharmacist involved in dispensing this product must be trained in the requirements of the Reddy-Lenalidomide RMP Program.
- Pharmacy should segregate LENANGIO (Lenalidomide) stock and position shelf tags to remind the pharmacy staff of dispensing instructions
- The prescription must not be dispensed unless it is written and signed by a registered prescriber and the prescriber ID number and patient ID number are documented on the prescription
- Confirm the days' supply prescribed does not exceed maximum permitted days, ie. no more than a 4-week (28-day) supply for females of child-bearing potential (12-weeks (84 days) for all other patients - males, females not of child-bearing potential). No automatic refills or telephone prescriptions allowed.
- Prior to dispensing each prescription, obtain a confirmation number from the Reddy-Lenalidomide RMP Singapore Contact Centre by sending the following information via email to **customerservice@zyfas.com:**
  - Pharmacy ID number, pharmacy/dispensing pharmacist information
  - Prescriber's ID number (written on the prescription)
  - Patient's ID number (written on the prescription)
  - Number of capsules and milligram strength being dispensed.

  The confirmation number will be sent to the pharmacy via email during office hours.
- When dispensing, ensure the confirmation number is documented on the prescription
- Medication must be dispensed to the patient within 7 days of the date of the prescription.
- Pharmacist must counsel the patient each time LENANGIO (Lenalidomide) is dispensed according to his/her risk category.
- Pharmacist must dispense LENANGIO (Lenalidomide) to patient along with the Patient Guide.

Classifying Patient Risk Categories

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 meet at least one of the following criteria:

- ≥ 50 years and naturally amenorrhoeic for ≥ 1 year (excluding amenorrhea from cancer therapy or during breastfeeding)
- Premature ovarian failure confirmed by a specialist gynaecologist
- Previous bilateral salpingo-oophorectomy, or hysterectomy
- XY genotype, Turner syndrome, uterine agenesis

3. **Male Patients**

Counselling messages

ALL PATIENTS
Patients must understand the importance of compliance with the conditions of use and must be capable of understanding and carrying out instructions. In some cases, the patient will need a competent support person to ensure program compliance.
Counsel your patients on all the potential side effects associated with Lenalidomide.

Patients should not donate blood during therapy and for at least 4 weeks after stopping the medication. Patients should be instructed never to give this medicinal product to another person and to return any unused capsules to their pharmacist at the end of treatment for safe disposal. Medication must also be kept out of reach of children.

Healthcare professionals and caregivers should wear disposable gloves when handling the blister or capsule. Women who are pregnant or suspect they may be pregnant should not handle the blister or capsule.

FEMALE PATIENTS OF CHILD-BEARING POTENTIAL
Inform your patients about the expected teratogenic risk and the strict pregnancy prevention measures as specified in the Pregnancy Prevention Programme and provide patients with appropriate patient educational brochure.

They must use 2 effective methods of contraception starting at least 4 weeks before therapy, during dose interruptions, during therapy and for at least 4 weeks following discontinuation of the medication, unless the patient commits to absolute and continuous abstinence confirmed on a monthly basis. If not established on effective contraception, the patient must be referred to an appropriately trained health care professional for contraceptive advice in order that contraception can be initiated. The following can be considered to be examples of suitable methods of contraception:

- Implant
- Levonorgestrel-releasing intrauterine system (IUS)
- Medroxyprogesterone acetate depot
- Tubal sterilisation
- Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses
- Ovulation inhibitory progesterone-only pills (i.e. desogestrel)

SS ARTS Graphic Designers

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New Artwork (06.09.2021)
Correction Done (27.08.2025)

PANTONE CODES	
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Patients should be instructed to consult a physician immediately if there is a risk of pregnancy. If pregnancy does occur during treatment, Lenalidomide must be discontinued immediately.
The use of combined oral contraceptive pills is not recommended due to the increased risk of venous thromboembolism in patients with multiple myeloma taking lenalidomide with or without dexamethasone. If a patient is currently using combined oral contraception, the patient should switch to one of the effective methods listed above. The risk of venous thromboembolism continues for 4−6 weeks after discontinuing combined oral contraception. The efficacy of contraceptive steroids may be reduced during co-treatment with dexamethasone.

Implants and levonorgestrel-releasing intrauterine systems are associated with an increased risk of infection at the time of insertion and irregular vaginal bleeding. Prophylactic antibiotics should be considered particularly in patients with neutropenia. Copper-releasing intrauterine devices are generally not recommended due to the potential risks of infection at the time of insertion and menstrual blood loss which may compromise patients with neutropenia or thrombocytopenia.

Pregnancy Tests

Patients must have medically supervised pregnancy tests performed by their registered prescriber as follows:
An initial pregnancy test on the day of the prescribing visit before starting therapy or in the 3 days prior to the visit to the prescriber once the patient had been using effect contraception for at least 4 weeks. Confirm the patient is not pregnant before starting treatment.
During treatment, pregnancy testing should be repeated every at least 4 weeks except in case of confirmed tubal sterilisation. These pregnancy tests should be performed on the day of the prescribing visit or in the 3 days prior to the visit to the prescriber.
A pregnancy test must also be conducted at least 4 weeks after stopping the treatment.
Inform patients about the need to commence the treatment as soon as lenalidomide is dispensed following a negative pregnancy test. Patients must immediately stop taking the medication and inform their prescriber if they become pregnant while taking the drug, miss a menstrual period, experience unusual bleeding or think for any reason they may be pregnant. In case of suspected pregnancy, patients should be referred to a physician specialized or experienced in teratology for evaluation and advice.

FEMALE PATIENTS NOT OF CHILD-BEARING POTENTIAL

Counsel on the risks of birth defects developing if an unborn baby is exposed to this medication.

ALL MALE PATIENTS

Inform patients about the expected teratogenic risk and the strict pregnancy prevention measures as specified in the Pregnancy Prevention Programme and provide patients with appropriate patient educational brochure. They should use condoms during treatment, during dose interruptions and for at least 4 weeks after they finish therapy if their partner is pregnant or of childbearing potential and has no contraception.

If the female partner of a male patient becomes pregnant whilst he is taking lenalidomide or shortly after he has stopped taking lenalidomide, he should inform his treating physician immediately and that it is recommended to refer the female partner to a physician specialised or experienced in teratology for evaluation and advice.

Steps to Completing Initial and Subsequent Prescriptions

Initial prescription

1. Prescribers must complete the Prescriber Registration form in order to enroll in the program and obtain a unique prescriber ID number.
2. Prescribers should determine the risk category of the patient and counsel according to this risk category (refer to separate section for all counselling messages).
3. Prescribers must provide each patient with patient- education material (including the most updated Patient Guide of the Reddy-Lenalidomide RMP program).
4. For females of reproductive potential, prescribers must obtain medically supervised negative pregnancy test sensitive to at least 25 mIU/mL, even if absolute and continuous abstinence is the chosen method of birth control. The test must be performed on the day of the prescribing visit prior to writing an initial prescription for LENANGIO .
5. Prescribers must complete the Informed Consent form with each patient in order to enroll in the program and obtain a unique patient ID number. Prescribers must keep a copy of this form for their records and send a copy via email, to **customerservice@zyfas.com**
6. Write and sign prescription and ensure it includes Prescriber ID, patient ID, and days' supply according to maximum permitted for the patient's risk category (4 weeks for FCBP and 12 weeks for all other patients). No automatic refills or telephone prescriptions are permitted.
7. Pharmacist verify that the prescription is valid:
   a. prescriber ID, patient ID is documented on the prescription
   b. days' supply prescribed according to maximum permitted for the patient's risk category (4 weeks for FCBP and 12 weeks for all other patients), and prescription was written within the last seven days
8. Pharmacist obtain a confirmation number by sending the following information to **customerservice@zyfas.com:**
   a. Pharmacy ID number, pharmacy/dispensing pharmacist information
   b. Prescriber's ID number
   c. Patient's ID number
   d. Number of capsules and milligram strength being dispensed.

   and document confirmation number on prescription.
9. Pharmacist should counsel the patient according to his/her risk category (refer to separate section for all counselling messages).
10. Pharmacist dispense the medication to the patient with the Patient Guide.

Subsequent prescriptions

1. For females of reproductive potential, prescribers must obtain scheduled medically supervised pregnancy tests every at least 4 weeks, except in case of demr noctubal sterilization. These pregnancy tests should be performed on the day of the prescribing visit or in the 3 days prior to the visit to the prescriber.
2. Prescribers should determine the risk category of the patient and counsel according to this risk category (refer to separate section for all counselling messages).
3. Write and sign prescription and ensure it includes Prescriber ID, patient ID, and days' supply according to maximum permitted for the patient's risk category (4 weeks for FCBP and 8 weeks for all other patients). No automatic refills or telephone prescriptions are permitted.
4. Pharmacist verify that the prescription is valid:
a. prescriber ID, patient ID is documented on the prescription
b. days' supply prescribed according to maximum permitted for the patient's risk category (4 weeks for FCBP and 12 weeks for all other patients), and prescription was written within the last seven days
5. Pharmacist obtain a confirmation number by sending the following information to **customerservice@zyfas.com:**
   a. Pharmacy ID number, pharmacy/dispensing pharmacist information
   b. Prescriber's ID number
   c. Patient's ID number
   d. Number of capsules and milligram strength being dispensed.

   and document confirmation number on prescription.
6. Pharmacist should counsel the patient according to his/her risk category (refer to separate section for all counselling messages).
7. Pharmacist dispense the medication to the patient with the Patient Guide.

Prescriber Enrollment in the Lenalidomide RMP Program

- Prescribers must obtain the Prescriber Registration Form by emailing to customerservice@zyfas.com
- Return the completed form through email at **customerservice@zyfas.com** in order to receive a unique prescriber ID number.

Pharmacy Enrollment in the Lenalidomide RMP Program

- Pharmacies must obtain the Pharmacy Registration Form by emailing to customerservice@zyfas.com
- Return the completed form through email at **customerservice@zyfas.com** in order to receive a unique Pharmacy ID number and login details.

Patient Enrollment in the Lenalidomide RMP Program

- Prescribers must obtain the Informed Consent Form by emailing to customerservice@zyfas.com
- Patient, parent/legal guardian, and/or authorized representative must read, understand and sign the Informed Consent Form
- Fill out the Informed Consent Form with the patient as directed
  - Initial only in the designated areas on the Informed Consent Form
  - The form must be completed and signed by both prescriber and patient
  - If the patient is under 21 years of age, his or her legal guardian must read and understand this material prior to the patient signing
- Instructions for Incompetent Adult Patients
  - For an incompetent adult patient, an authorized representative must sign the Informed Consent Form
  - An authorized representative is a caretaker authorized under applicable law in the country to consent to treatment on the incompetent patient's behalf
  - The authorized representative must read the material, initial the appropriate statements, and agree to ensure compliance by signing and dating the form
- Return the completed form via email to **customerservice@zyfas.com** in order to receive a unique patient ID number.

Note: If therapy with LENANGIO (Lenalidomide) is discontinued, the patient must be enrolled again in the Reddy-Lenalidomide RMP Program. Follow the above procedures to re-enroll the patient.

Prescriber Requirements for Prescriptions

- Obtain a medically supervised **negative** pregnancy test on the same day of the prescribing visit prior to writing an initial prescription for Lenalidomide even if absolute or continuous abstinence is the chosen method of birth control. The pregnancy test must be sensitive to at least 25 mIU/mL.
- Prescribe no more than 4 weeks (28 days) of therapy, with no refills for females of child-bearing potential. Note: max 12 weeks (84 days) can be prescribed for all other patients - males, females not of child-bearing potential.

Prescriber should have their prescriber ID, their patient's ID number, and the days' supply written on the prescription.

Reporting Pregnancy

If pregnancy is suspected or does occur during treatment, the prescriber must inform the Reddy- Lenalidomide RMP Singapore Contact Centre at **+65 6275 7757**, or through email at **customerservice@zyfas.com.**

The Reddy-Lenalidomide RMP Singapore Contact Centre will send the Pregnancy Report Form for the prescriber to complete and will follow-up on the progress of all pregnancies occurring under LENANGIO (Lenalidomide) treatment.

Reporting Adverse Event

REPORTING TO LENANGIO PRODUCT REGISTRANT DRUG SAFETY CONTACT
ZYFAS PHARMA PTE LTD
102F Pasir Panjang Road #06-10
Citilink Warehouse Complex .
Singapore 118530

Email for adverse event reporting: customerservice@zyfas.com Telephone for adverse event reporting: +6562757757

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