Dr.Reddy's

**This material was developed by Dr. Reddy's Laboratories, as part of the risk minimization plan for Reddy-Lenalidomide and Reddy-Pomalidomide. This material is not intended for promotional use.**

# Reddy-Lenalidomide RMP Program and Reddy-Pomalidomide RMP Program: Pharmacy Guide

## ➢ Reddy-Lenalidomide

## Indication:

Reddy-Lenalidomide is indicated for the treatment of patients with transfusion-dependent anemia due to Low- or Intermediate-1-risk myelodysplastic syndromes associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities. Approval for this indication is based on red blood cell transfusion independence response rates. Overall survival benefit has not been demonstrated.

Reddy-Lenalidomide in combination with dexamethasone is indicated for the treatment of multiple myeloma patients who are not eligible for stem cell transplant.

**Limitation of Use:** Reddy-Lenalidomide is not indicated and is not recommended for the treatment of patients with chronic lymphocytic leukemia (CLL) outside of controlled clinical trials.

## Risks:

**Reddy-Lenalidomide has a Boxed Warning for embryo-fetal toxicity, hematologic toxicity, and deep venous thrombosis (DVT) and pulmonary embolism (PE) as well as risk of myocardial infarction and stroke.**

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

**There is a significant risk of deep venous thrombosis and pulmonary embolism as well as risk of myocardial infarction and stroke** in patients with multiple myeloma taking Reddy-Lenalidomide plus dexamethasone in combination. Monitor for and advise patients about the signs and symptoms of thromboembolism.

Advise patients to seek immediate medical care if they develop symptoms such as shortness of breath, chest pain, or arm or leg swelling. Thromboprophylaxis is recommended and the choice of regimen should be based on an assessment of the patient's underlying risks.

**Secondary tumors such as skin cancers, blood cancers, and solid tumor cancers** have been reported in a small number of patients taking Reddy-Lenalidomide or after treatment with Reddy-Lenalidomide is completed. Patients should talk to their doctors if they have any concerns about their own increased risk of having other cancers. The risk of occurrence of secondary primary malignancies must be taken into account before initiating treatment with Reddy-Lenalidomide. Physicians should carefully evaluate patients before and during treatment using standard cancer screening for occurrence of second primary malignancies and institute treatment as indicated.

**There is a high risk of liver problems in patients taking Reddy-Lenalidomide, which may cause death.** Before you use Reddy-Lenalidomide, talk to your doctor if you have liver problems. Monitor liver enzymes periodically if taking Reddy-Lenalidomide. Stop Reddy-Lenalidomide upon elevation of liver enzymes. After return to baseline values, treatment at a lower dose may be considered.

**This is not a comprehensive description of the risks associated with the use of Reddy-Lenalidomide. Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed, for further information regarding the use of Reddy-Lenalidomide**

## Contraindications

- Reddy-Lenalidomide is contraindicated in patients who are hypersensitive to it or to thalidomide, pomalidomide or to any ingredient in the formulation or component of the container.

- Reddy-Lenalidomide is contraindicated in pregnant women and women at risk of becoming pregnant. Reddy-Lenalidomide is structurally related to thalidomide, a known human teratogen that causes severe and life-threatening birth defects. Reddy-Lenalidomide induced malformations in monkeys similar to those described with thalidomide. If Reddy-Lenalidomide is taken during pregnancy, it may cause severe birth defects or death to the fetus. Females of child-bearing potential may be treated with Reddy-Lenalidomide provided that adequate contraception, with two simultaneous effective methods of contraception, is used to prevent fetal exposure to the drug. The choice of the two simultaneously effective contraceptive methods will necessitate a risk/benefit discussion between the patient and a specially trained pharmacist

- Reddy-Lenalidomide is contraindicated in breastfeeding women.

- Reddy-Lenalidomide is contraindicated in male patients unable to follow or comply with the required contraceptive measures.

- Reddy-Lenalidomide treatment should not be started in patients whose platelet levels are less than 50 x 109/L.

# ➢ Reddy-Pomalidomide

## Indication:

Reddy-Pomalidomide in combination with dexamethasone (dex) and Bortezomib is indicated in the treatment of adult patients with multiple myeloma (MM) who have received at least one prior treatment regimen that included Lenalidomide.

Reddy-Pomalidomide in combination with dexamethasone is indicated for patients with multiple myeloma for whom both Bortezomib and Lenalidomide have failed and who have received at least two prior treatment regimens and have demonstrated disease progression on the last regimen.

## Risks:

**Reddy-Pomalidomide has a Boxed Warning for embryo-fetal toxicity, hematologic toxicity, and deep venous thrombosis (DVT) and pulmonary embolism (PE) as well as risk of myocardial infarction and stroke.**

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

**The use of Reddy-Pomalidomide in combination with dexamethasone ± bortezomib for the treatment of MM results in an increased risk of venous thromboembolic events (VTE), such as deep vein thrombosis (DVT) and pulmonary embolism (PE).** Previous history of thromboembolic events or concomitant administration of erythropoietic agents or other agents such as hormone replacement therapy, may also increase thrombotic risk. Therefore, these agents should be used with caution in MM patients receiving Reddy-Pomalidomide in combination with dexamethasone ± bortezomib. The use of hormonal contraceptives is associated with an increased risk of thromboembolic disorders. Hormonal contraceptives are not recommended (see Special Populations, Females of Child-Bearing Potential). Prophylactic antithrombotic medications, such as low dose aspirin, low molecular weight heparins or warfarin, should be recommended.

**Second primary malignancies (SPM), including non-melanoma skin cancer, have been reported in patients receiving Reddy-Pomalidomide.** The clinical significance of these observations is unclear. Physicians should carefully evaluate patients before and during treatment using standard cancer screening for occurrence of SPM and institute treatment as indicated.

**Decreased blood cell counts, including neutropenia, anemia, or thrombocytopenia, including Grade 3 or 4 occurrences, have been reported in association with the clinical use of Reddy-Pomalidomide in combination with dexamethasone ± bortezomib.** Monitor patients for hematologic toxicities, especially neutropenia and thrombocytopenia. Patients should be advised to report febrile episodes promptly. Monitor complete blood counts weekly for the first 8 weeks and monthly thereafter. Patients may require dose interruption and/or modification. Patients may require use of blood product support and/or growth factors. Patients and physicians are advised to be observant for signs and symptoms of bleeding including epistaxis, especially in case of concomitant medication susceptible to induce bleeding.

**This is not a comprehensive description of the risks associated with the use of Reddy-Pomalidomide. Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed, for further information regarding the use of Reddy-Pomalidomide.**

## Contraindications

- Reddy- Pomalidomide is contraindicated in patients who are hypersensitive to it or to thalidomide, pomalidomide or to any ingredient in the formulation or component of the container.

- Reddy- Pomalidomide is contraindicated in pregnant women and women at risk of becoming pregnant. Reddy- Pomalidomide is structurally related to thalidomide, a known human teratogen that causes severe and life-threatening birth defects. Reddy- Pomalidomide induced malformations in monkeys similar to those described with thalidomide. If Reddy- Pomalidomide is taken during pregnancy, it may cause severe birth defects or death to the fetus. Females of child-bearing potential may be treated with Reddy- Pomalidomide provided that adequate contraception, with two simultaneous effective methods of contraception, is used to prevent fetal exposure to the drug. The choice of the two simultaneously effective contraceptive methods will necessitate a risk/benefit discussion between the patient and a specially trained pharmacist

- Reddy- Pomalidomide is contraindicated in breastfeeding women.

- Reddy- Pomalidomide is contraindicated in male patients unable to follow or comply with the required contraceptive measures.

## Goals of the Reddy-Lenalidomide RMP Program and Reddy-Pomalidomide RMP Program:

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

## About the Reddy-Lenalidomide RMP Program and Reddy-Pomalidomide RMP Program:

Due to their structural similarity to thalidomide, a known teratogen, Reddy-Lenalidomide and Reddy-Pomalidomide are marketed only under controlled distribution programs. The programs are called the Reddy-Lenalidomide RMP Program for Reddy-Lenalidomide and the Reddy Pomalidomide RMP Program for Reddy-Pomalidomide. This is a requirement by Health Canada for Reddy-Lenalidomide and Reddy-Pomalidomide to ensure that the benefits of these drugs outweigh the risk of embryo-fetal exposure to Reddy-Lenalidomide and Reddy-Pomalidomide, as well as to inform prescribers, patients, and pharmacists on the serious risks and safe-use conditions for Reddy-Lenalidomide and Reddy-Pomalidomide. To avoid embryo-fetal toxicity, Reddy-Lenalidomide or Reddy-Pomalidomide will only be available under the Reddy-Lenalidomide RMP Program and Reddy-Pomalidomide RMP Program. Only registered prescribers and pharmacies in the Reddy-Lenalidomide RMP Program and Reddy-Pomalidomide RMP program can prescribe or dispense these medications. In order to receive Reddy-Lenalidomide or Reddy-Pomalidomide, all patients must be enrolled in the Reddy-Lenalidomide RMP program or Reddy-Pomalidomide RMP program and agree to comply with the requirements of the respective programs.

Information about Reddy-Lenalidomide and Reddy-Pomalidomide and their respective Risk Management Programs can be obtained by calling for assistance at **1-877-938-0670,** or through the website (**www.reddy2assist.com**).

## Key Points

- To enroll in the Reddy-Lenalidomide RMP program and Reddy-Pomalidomide RMP program and to dispense Reddy-Lenalidomide or Reddy-Pomalidomide, pharmacies must complete and return the Pharmacy Registration Form to Dr. Reddy's Laboratories Canada Inc. via email, fax or mail to:

  **Rx Infinity, Attn: Reddy2Assist Program**
  **5155 Spectrum Way, Unit 29,**
  **Mississauga ON L4W 5A1**
  **Phone: 1-877-938-0670**
  **Fax: 1-877-938-0807**
  **Email: reddy2assist@drreddys.com**
  **Website: www.reddy2assist.com**

- Every pharmacist involved in dispensing these products must be trained in the requirements of the controlled distribution programs and be compliant with the programs.

- All pharmacy staff must comply with the requirements of the programs and have sufficient expertise to deliver the required counselling services. Failure to comply with the requirements of the programs may result in termination of their participation in the programs.

- The prescription must not be accepted unless it is written and signed by a registered prescriber and the prescriber ID number and patient ID number are documented on the prescription and the days' supply prescriber does not exceed maximum permitted for the patient's risk category. The patient's risk category can be verified online at **www.reddy2assist.com**, or by calling the respective RMP Program Contact Centers for assistance at **1-877-938-0670**.

- Confirm the prescription is no more than a 4-week (28-day) supply for females of child-bearing potential (84 days for all other patients - males, females not of child-bearing potential). No refills or telephone prescriptions allowed

- Obtain a confirmation number from the Reddy-Lenalidomide RMP Program and Reddy-Pomalidomide RMP Program online at **www.reddy2assist.com** or by phone at **1-877-938-0670**.

- For females of child-bearing potential, prescriptions **must** be dispensed within 7 days of the last negative pregnancy test, which should coincide with the expiry date of the confirmation number (24 hours)

- Medication must be dispensed to the patient before confirmation number expires: 24 hours from the date the confirmation number is generated for Females of child-bearing potential and 14 days from the date the confirmation number is generated for all other patients.

- When dispensing, ensure the Reddy-Lenalidomide lot number and Reddy-Pomalidomide lot number and confirmation number are documented on their respective prescription

- A program trained Pharmacist must counsel the male patient and female patient of childbearing potential each time Reddy-Lenalidomide or Reddy-Pomalidomide is dispensed according to his/her risk category and document this on the respective prescription. Emergency contraception counselling to the patient must be provided by the pharmacist if necessary and the pharmacist must inform the respective RMP Program Contact Centers and the prescriber if a patient or a patient's partner becomes pregnant

- Pharmacist must dispense Reddy-Lenalidomide or Reddy-Pomalidomide to patient along with their respective "Part III of the Product Monograph: Consumer Information"

- Confirmation number must be cancelled if no medication is provided to the patient. If confirmation number expires and the patient still requires the medication, you must cancel the confirmation number by calling the respective Programs and a new confirmation number must be generated.

## Guidelines for Counselling, and Dispensing Reddy- Lenalidomide or Reddy-Pomalidomide

Dispensing pharmacies must be registered in the Reddy-Lenalidomide RMP Program and Reddy-Pomalidomide RMP Program and must be educated in the following dispensing procedures.

**Step 1. Verify that the prescription is valid by verifying prescriber ID, patient ID and days' supply prescribed for all incoming Reddy-Lenalidomide and Reddy-Pomalidomide prescriptions**

- Only accept prescriptions written and signed by a registered prescriber. The prescription must not be accepted unless the prescriber ID number, patient ID number is written on the prescription

- The registered pharmacy can verify the patient risk category online or by calling the respective RMP Program Contact Centers for assistance at **1-877-938-0670** for each prescription before dispensing

- Notify the prescriber and the Reddy-Lenalidomide RMP Program or Reddy-Pomalidomide RMP Program as soon as you know a female child has reached menarche. Counsel the patient according to the requirements of the respective programs and document changes on the prescription.

- Confirm the prescription is no more than a 4-week (28-day) supply for females of child-bearing potential (84 days for all other patients - males, females not of child-bearing potential)

- For females of child-bearing potential, prescriptions **must be dispensed within 7 days** of the last negative pregnancy test, which should coincide with the expiry date of the confirmation number (24 hours)

    - Dispensing should occur **within 24 hours** of the pharmacist obtaining the confirmation number, including for subsequent prescriptions to ensure that dispensing aligns within 7 days of the last pregnancy test

- For all other patients, dispensing should occur within 14 days of the date the confirmation number is generated

- Prior to dispensing each prescription, obtain a confirmation number by entering applicable information through RMP Program website (**www.reddy2assist.com**) or contact the respective RMP Program Contact Centers **1-877-938-0670** for assistance. Be prepared to enter some of the following information:

    - Dispensing pharmacy information/dispensing pharmacist information

    - Prescriber's ID number (written on the prescription)

    - Patient's ID number (written on the prescription)

    - Enter the number of capsules and milligram strength being dispensed. Total number of days supply should not exceed 28 days for females of child-bearing potential. Note: max 84 days for all other patients - males, females not of child-bearing potential. No refills or telephone prescriptions are allowed

- For FCBP, ensure that dispensing occurs **within 7 days** of the date of the prescription, and **24 hours** of obtaining the confirmation number. This applies to all subsequent prescriptions.

**Step 2. Counsel patient**

- Counsel the patient (male patients and female patients of childbearing potential) at every dispense, and document this on the prescription.

    - See: "Counselling Tool for Pharmacist"

- Important Counselling to reiterate to patient:

    - Instruct your patients on why and how they and their partners should prevent pregnancy to avoid the risk of teratogenicity, birth defects and/or fetal death

- Every new patient who is a Female of child-bearing potential should have had a consultation on contraceptive options with a specially trained pharmacist so that they can fully understand the need to use **TWO** simultaneous effective (one highly effective and one effective) methods of contraception starting at least 4 weeks before therapy, during dose interruptions, during therapy and for 4 weeks following discontinuation of the medication. Patients should be instructed to consult a physician immediately if there is a risk of pregnancy. If pregnancy does occur during the treatment with Reddy-Lenalidomide or Reddy-Pomalidomide then the treatment must be discontinued immediately

- Instruct your patients on all the potential side effects associated with Reddy-Lenalidomide or Reddy-Pomalidomide according to their respective treatment.

- Inform them that they should NEVER donate blood during and for 4 weeks after stopping the medication and that they should never share the medication with anyone else, even if the person has similar symptoms. Male patient should also not donate sperm during and for 4 weeks after stopping the medication as well

- Counsel your patients on understanding the risk of contraception failure, the available options for emergency contraception and inform your patients to notify the respective programs immediately if they or their partner becomes pregnant

- Patients should be instructed not to extensively handle or open Reddy-Lenalidomide capsules and Reddy-Pomalidomide capsules. They must maintain the product in its original packaging until ingested and they must wash any affected areas that may come into direct contact with non-intact capsules or their contacts using soap and water. Any woman who is pregnant or who can get pregnant must wear latex gloves when handling the medication

- Provide additional counseling upon request to patients and/or guardians of patients under 18 years of age receiving Reddy-Lenalidomide or Reddy-Pomalidomide treatment. Any suspected pregnancy occurring during the treatment with Reddy-Lenalidomide or Reddy-Pomalidomide, should be reported to the Reddy-Lenalidomide RMP program or Reddy-Pomalidomide RMP program.

**Step 3. Dispensing**

- A new prescription is required each time you dispense Reddy-Lenalidomide or Reddy-Pomalidomide, as there are no refills allowed. Follow all steps to dispense initial prescription and all subsequent prescriptions thereafter

- Obtain a confirmation number and dispense or ship **within 24 hours** for females of child-bearing potential. For all other patients, dispensing/shipping should occur **within 14 days** of the generation of the confirmation number. **Do Not Dispense** if past the maximum timeframe

- When dispensing, ensure the Reddy-Lenalidomide lot number and Reddy-Pomalidomide lot number, and confirmation number are documented on their respective prescription

- Dispense each prescription of Reddy-Lenalidomide or Reddy-Pomalidomide with their respective Part III of the Product Monograph: Consumer Information and maintain a record on acceptable documentation

    - Acceptable documentation examples:

        - Pharmacy log

- Document the dispense date and maintain a record on acceptable documentation with sufficient details to ensure compliancy

    - Acceptable documentation examples:

- Shipping receipt
- Pharmacy dispensing log

- Dispense no more than a 4-week (28-day) supply for females of child-bearing potential. The prescription can be written for up to an 84 day supply for all other patients (males, females not of child-bearing potential)
- **No refills or telephone prescriptions are permitted**
- A signature is required from the dispensing pharmacist to ship Reddy-Lenalidomide or Reddy-Pomalidomide, and/or to dispense to a patient
- Ensure the prescribed medication (either Reddy-Lenalidomide or Reddy-Pomalidomide) is shipped the same day those are dispensed (within 24 hours), especially for females of child-bearing potential
    - Couriers must deliver the medication to the patient within 24 hours and the process must include a mechanism to track shipments and require signature for delivery

**Step 4. Perform drug accountability**

- Pharmacy shall keep respective inventory log for Reddy-Lenalidomide and for Reddy-Pomalidomide, by strength, reflecting its on-hand inventory at all times.
- You should segregate Reddy-Lenalidomide and Reddy-Pomalidomide stock (ie. with other thalidomide, pomalidomide, and lenalidomide products) and position shelf tags to remind the pharmacy staff of dispensing instructions
- Do not transfer Reddy-Lenalidomide or Reddy-Pomalidomide to another pharmacy without authorization from the respective RMP Programs. Contact the respective RMP Program Contact Centers at **1-877-938-0670** for further assistance
- Properly accept and dispose of unused Reddy-Lenalidomide or Reddy-Pomalidomide (previously dispensed) from a patient or patient caregiver
- Return to Dr. Reddy's all Reddy-Lenalidomide capsules and Reddy-Pomalidomide capsules that are returned by patients. Shipping fees will be paid by Dr. Reddy's. To arrange returns, call **1-877-938-0670**

## Rules for Dispensing and Shipping – Final Check

DO NOT DISPENSE OR SHIP REDDY-LENALIDOMIDE OR REDDY-POMALIDOMIDE TO A PATIENT UNLESS ALL OF THE FOLLOWING STEPS ARE COMPLETED:

- Courier dispensed medications must be delivered within 24h with tracking and signature
- For females of child bearing potential, you must ship the product on the same day the confirmation number is generated.
- The respective Reddy-Lenalidomide Part III of the Product Monograph: Consumer Information or Reddy-Pomalidomide - Part III of the Product Monograph: Consumer Information is included with the respective prescription being dispensed
- You confirm the prescription is no more than a 4-week (28-day) supply for females of child-bearing potential (84 days for all other patients - males, females not of child-bearing potential) and there are 7 days or less remaining on the existing Reddy-Lenalidomide or Reddy-Pomalidomide prescription

**For further information about Reddy-Lenalidomide and Reddy-Pomalidomide, please refer to their respective full Prescribing Information, enclosed.**

**Special Handling Instructions**

- Health care professionals should consider wearing latex gloves while handling Reddy-Lenalidomide or Reddy-Pomalidomide.
- For FCBP, it is necessary to wear latex gloves while handling Reddy-Lenalidomide or Reddy-Pomalidomide.
    - FCBP should also avoid extensively handling or opening the capsules. If a FCBP comes into contact with the powder contents of the medication, immediately wash your hands.
- Repackaging of the medication should only be done in exceptional circumstances and only be pharmacists.

**Pregnancy reporting**

Any suspected pregnancy in a female patient or female partner of a male patient should be immediately reported to the prescriber and the respective RMP programs at **1-877-938-0670.**

## Adverse Event Reporting

**REPORTING TO REDDY-LENALIDOMIDE RMP PROGRAM AND REDDY-POMALIDOMIDE RMP PROGRAM CONTACT CENTER**

**Rx Infinity, Attn: Reddy2Assist Program**
**5155 Spectrum Way, Unit 29,**
**Mississauga ON L4W 5A1**
**Phone: 1-877-938-0670**
**Fax: 1-877-938-0807**
**Email: reddy2assist@drreddys.com**
**Website: www.reddy2assist.com**

**REPORTING TO HEALTH CANADA**

Adverse events suspected to be associated with the use of Reddy-Lenalidomide or Reddy-Pomalidomide may be reported to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhpmps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax; or calling toll-free at 1-866-234-2345.
- Report adverse drug experiences that are suspected to be associated with the use of Reddy-Lenalidomide or Reddy-Pomalidomide by one of the methods above within 24 hours.

For more information about Reddy-Lenalidomide and Reddy-Pomalidomide, and their respective Risk Management Programs, please visit www.reddy2assist.com or call for assistance at **1-877-938-0670**.

**Reddy-Lenalidomide and Reddy-Pomalidomide are only available through the Reddy-Lenalidomide RMP Program and Reddy-Pomalidomide RMP Program, restricted distribution programs.**

**Please see respective Prescribing Information, including BOXED WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS, and Medication Guide, enclosed.**