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: Prescriber 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 qualified physician experienced in the use of contraceptive methods.

- 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 10^9/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 qualified physician experienced in the use of contraceptive methods.

- 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:

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, 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 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 for the Prescriber

- To enroll in the Reddy-Lenalidomide RMP program and Reddy-Pomalidomide RMP program and to prescribe Reddy-Lenalidomide or Reddy-Pomalidomide, all prescribers must complete and return the Prescriber Registration Form to receive a unique prescriber ID number.

- The prescriber must counsel patient on benefits and risks of their respective treatment (Reddy-Lenalidomide or Reddy-Pomalidomide), and on the safe use of drug at every visit.

- The prescriber determines the patient risk category and completes the respective 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 to Dr. Reddy's Laboratories Canada Inc. via email, fax or mail to:
  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

- 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 Reddy-Lenalidomide therapy or Reddy-Pomalidomide therapy immediately to the respective RMP Program Contact Centers.

    - The prescriber and patient (female of child-bearing potential only) completes applicable mandatory confidential survey online or by telephone (initially and monthly thereafter)

    - Once the patient has been registered and counselled the prescriber should:

        - As part of the prescription processing:
            - For FBCP: Request pregnancy tests and confirm negative status to the program through prescriber survey
            - 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 (84 days for all other patients - males, females not of child-bearing potential) (no automatic refills or telephone prescriptions)

    - Include your unique prescriber ID number and your patient's unique ID number, on every prescription written for Reddy-Lenalidomide or Reddy-Pomalidomide

    - The prescriber sends respective prescription to a registered pharmacy. The registered pharmacy will contact patients for mandatory counseling (for FCBP and male patients at every dispense) and coordinate delivery of Reddy-Lenalidomide or Reddy-Pomalidomide to the patient after verifying that the patient's negative pregnancy status with the respective RMP Program Contact Centers and obtaining a confirmation number.

    - Important note: Be advised to wear gloves if and when directly handling the product to avoid unintentional exposure

Classifying Patient Risk Categories

***Note:** *(For patients less than 19 years old)* - If they have not reached puberty or menses, they must notify the respective RMP Program Contact Centers at 1-877-938-0670, or through the website (**www.reddy2assist.com**) when such change occurs and both the patient and prescriber must follow the requirements of the respective programs based on the reclassification

1. **Females of Child-Bearing Potential**

    - Females who are menstruating, amenorrheic from previous medical treatments, and/or perimenopausal, and do not qualify for the females not of child-bearing potential category

2. **Females Not of Child-Bearing Potential**

    - Females who have been in natural menopause for at least 12 consecutive months (excluding amenorrhea from cancer therapy), females with a previous hysterectomy or bilateral oophorectomy; females who have premature ovarian failure confirmed by a gynecologist, females who are XY genotype, who have Turner syndrome or uterine agenesis and

prepubertal females who have not started menstruating.

3. **Male Patients**

Counselling messages

ALL PATIENTS	**FEMALES NOT OF CHILD BEARING POTENTIAL**
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 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. Medication must also be kept out of reach of children. Patients should be instructed not to extensively handle or open Reddy-Lenalidomide capsules or Reddy-Pomalidomide capsules. They must maintain the product in its original packaging until ingested and they must wash (using soap and water) any affected areas which may come into direct contact with non-intact capsules. Patients should also inform caregivers assisting them with their medication who are or can become pregnant that they must handle the capsules with latex gloves	Counsel FNCBP on the risks of birth defects developing if an unborn baby is exposed to this medication. FNCBP should inform their pharmacist or prescriber immediately if their risk category changes (i.e. patient begins menses). **ALL PATIENTS LESS THAN 19 YEARS OLD** If the patient (male or female) has not reached puberty or menses, they must agree to notify the respective RMP Program Contact Centers at **1-877-938-0670**, or through the RMP Program website (**www.reddy2assist.com**) when such change occurs and follow the requirements of the respective programs based on the patient's reclassification.
FEMALES OF CHILD-BEARING POTENTIAL	**ALL MALES**
Instruct your patients on why and how they and their partners should prevent pregnancy to avoid the risk of teratogenicity, birth defects or fetal death. They must use at least 2 effective methods of contraception (at least one highly effective method and one effective method) at the same time every time they have sex with a man or completely abstain from heterosexual sexual conduct. Every new patient who is a female of child-bearing potential should have a consultation on contraceptive options with a qualified physician experienced in the use of contraceptive methods so that they can fully understand the need to use TWO simultaneous effective methods of contraceptives starting at least 4 weeks before therapy,	Must inform their sexual partner who are or can become pregnant that they are taking the medication and that unborn babies may develop birth defects if exposed to the medication through the semen of male patients. Instruct your patients on why and how they and their partners should prevent pregnancy. Also, inform them not to not to donate sperm, and the importance about appropriate contraceptive use. They should never donate semen (sperm) while taking, and for 4 weeks after stopping therapy. All male patients should completely abstain from sexual contact with females who are or can become pregnant or use a condom during any sexual contact with females of child-bearing potential, even if they have undergone a successful vasectomy. They should use condoms during treatment, during dose

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 treatment, then the respective treatment (Reddy-Lenalidomide or Reddy-Pomalidomide) must be discontinued immediately. The use of hormonal contraception is not recommended. Patient should understand the cumulative risks of deep venous thrombosis including, but not limited to, steroids, cancer and hormonal contraception. Patient should understand the importance of compliance with all the conditions of use. **Pregnancy Tests** Patients must have serum pregnancy tests performed by their registered prescriber as follows: An initial pregnancy test within 7-14 days before starting therapy. Confirm the patient is not pregnant with a second pregnancy test within 24 hours prior to writing an initial prescription. The patient must have two negative pregnancy tests before starting treatment. During treatment, pregnancy testing should be repeated weekly during the first 4 weeks of use; then pregnancy testing should be repeated every 4 weeks in females with regular or no menstrual cycles. If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks. A pregnancy test must also be conducted 4 weeks after stopping the treatment. Patients must immediately stop taking the medication and inform their prescriber and dispensing pharmacy 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 undergo pregnancy testing and consultation with an Obstetrician/Gynecologist	interruptions and for 4 weeks after they or their partner finishes therapy. In addition to the male using condoms, the patient's female partner should use another method of contraception for extra protection. Patients must inform their prescriber and dispensing pharmacy if they have unprotected sexual contact with a female who is pregnant or if they think their partner is pregnant. **Complete Mandatory Confidential Survey** Males will not need to complete any survey in order to obtain initial and following prescriptions.

Steps to Completing Initial and Subsequent Prescriptions

Initial prescription (for all patients unless otherwise noted)	Subsequent prescriptions (for all patients unless otherwise noted)
1. Prescribers must obtain, review and complete the Prescriber Registration form	1. For females of reproductive potential, obtain scheduled pregnancy tests

Initial prescription (for all patients unless otherwise noted)	Subsequent prescriptions (for all patients unless otherwise noted)
online at **www.reddy2assist.com**, or by calling the respective RMP Program Contact Centers for assistance at 1-877-938-0670 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. For females of reproductive potential, prescribers must obtain 2 negative pregnancy tests sensitive to at least 25 mIU/mL, even if continuous abstinence is the chosen method of birth control. The first test must be obtained 7 to 14 days before writing an initial prescription and the second test must be within 24 hours prior to writing an initial prescription for respective treatment (Reddy-Lenalidomide or Reddy-Pomalidomide). 4. Prescribers must obtain, review, and complete the appropriate Informed Consent form with each patient online at **www.reddy2assist.com**, or by calling the respective RMP Program Contact Centers for assistance at **1-877-938-0670** 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 to Dr. Reddy's Laboratories Canada Inc. via email, fax or mail: **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** 5. Females of child-bearing potential and prescribers must complete surveys initially and monthly thereafter in order to obtain subsequent prescriptions. The survey can be accessed via the patient portal at **www.reddy2assist.com** or via phone by calling 1-877-938-0670. 6. Prescribers must complete a mandatory survey as soon as the second pregnancy	weekly during the first 4 weeks of use; then pregnancy testing should be repeated every 4 weeks in females with regular menstrual cycles. If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks. 2. Provide mandatory counseling (refer to separate section for all counselling messages). 3. Females of child-bearing potential require a new prescription each month and will need to complete a brief survey by phone or online prior to each dispense. Prescribers will also need to complete a mandatory survey by phone or online to communicate the results of the last pregnancy test to the respective RMP Program Contact Centers. 4. 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 (28 days for FCBP and 84 for all other patients). 5. No automatic refills or telephone prescriptions are permitted. 6. Send the prescription to a registered pharmacy enrolled in the Reddy-Lenalidomide RMP Program or Reddy-Pomalidomide RMP Program. For FCBP, the medication must be dispensed to the patient within 7 days of the last negative pregnancy test.

Initial prescription (for all patients unless otherwise noted)	Subsequent prescriptions (for all patients unless otherwise noted)
test results are available and submit the survey to the respective RMP Program Contact Centers. 7. 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 (28 days for FCBP and 84 for all other patients). 8. No automatic refills or telephone prescriptions are permitted. 9. Send the prescription to a registered pharmacy enrolled in the Reddy-Lenalidomide RMP Program or Reddy-Pomalidomide RMP Program. For FCBP, the medication must be dispensed to the patient within 7 days of the last negative pregnancy test.	

Prescriber Enrollment in the Reddy-Lenalidomide RMP Program and Reddy-Pomalidomide RMP Program

- Prescribers must obtain, review, and complete the Prescriber Registration Form by accessing the RMP Program website at **www.reddy2assist.com** or by calling **1-877-938-0670**
- Prescribers who do not have access to a computer can call **1-877-938-0670** for additional assistance
- Return the completed form to Dr. Reddy's Laboratories Canada Inc. via email, fax or mail in order to receive a unique prescriber ID number:
  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

Patient Enrollment in the Reddy-Lenalidomide RMP Program or Reddy-Pomalidomide RMP Program

Prescribers must obtain, review, and complete the respective Informed Consent Form (Reddy-Lenalidomide or Reddy-Pomalidomide) with each patient by accessing the RMP Program website at **www.reddy2assist.com** or by calling **1-877-938-0670** for assistance

- Prescribers who do not have access to a computer can call **1-877-938-0670** for additional assistance
- Patient, parent/legal guardian, and/or authorized representative must read, understand and sign

the respective Informed Consent Form

- Help ensure timely processing of each prescription by filling out the respective 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
    - For female patients, the prescriber will need to provide information on whether the patient has been in surgical menopause, chemical menopause, or natural menopause for at least 12 months
    - If the patient is under 18 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 state law 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 to Dr. Reddy's Laboratories Canada Inc. via email, fax or mail in order to receive a unique patient ID number:
  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

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

Additional Requirements for Females of Child-Bearing Potential

Pregnancy test requirements

- Obtain a **negative** pregnancy test 7 to 14 days prior to writing an initial prescription for the respective treatment and again within 24 hours prior to writing an initial prescription for the respective treatment even if continuous abstinence is the chosen method of birth control
    - The pregnancy test must be sensitive to at least 25 mIU/mL
    - For females of reproductive potential, obtain scheduled pregnancy tests weekly during the first 4 weeks of use; then pregnancy testing should be repeated every 4 weeks in females with regular menstrual cycles. If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks.
        - If a patient misses her period or if there is any abnormality in menstrual bleeding, Reddy-Lenalidomide or Reddy-Pomalidomide should be discontinued immediately. Obtain a pregnancy test and counsel the patient
            - If pregnancy is suspected or does occur during treatment, the prescriber must inform the Reddy-Lenalidomide RMP Program or Reddy-Pomalidomide RMP Program and complete the **Pregnancy Report Form**.

Contraception Requirements

- Female patients of reproductive potential must either completely abstain from heterosexual sexual contact or must use 2 methods of reliable contraception (noted below):

    - The 2 effective contraceptive methods include using at the same time at least 1 highly effective method and at least 1 additional method of birth control every time they have sex with a male

The 2 effective contraceptive methods must be started at least 4 weeks before Reddy-Lenalidomide therapy or Reddy-Pomalidomide therapy, during therapy (including dose interruptions), and for at least 4 weeks following discontinuation of therapy

Effective Methods of Birth Control Used at the Same Time

Highly effective birth control methods	PLUS	Additional effective birth control methods
• Intrauterine device (IUD) • Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants)* • Tubal ligation (having your tubes tied) • Partner's vasectomy (tying of the tubes to prevent the passing of sperm)	+	• Male latex or synthetic condom • Diaphragm • Cervical cap
Unacceptable forms of contraception		
• Progesterone-only "mini-pills" • IUD Progesterone T • Female condoms • Natural family planning (rhythm method) or breastfeeding		• Fertility awareness • Withdrawal • Cervical shield (a cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception)

Hormonal methods of birth control are **not recommended due to increased risk of venous thromboembolic disease.*

- Remind all patients that not having any sexual intercourse is the only birth control method that is **100%** effective.
- Patients should be counseled that concomitant use of certain prescription drugs and/or dietary supplements can decrease the effects of hormonal contraception. If hormonal or IUD is medically contraindicated, 2 other contraceptive methods may be used simultaneously during periods of concomitant use and for 4 weeks after.

Mandatory Confidential Patient Surveys

Females

- Only Females of Child-Bearing Potential are required to complete a mandatory confidential patient survey initially and monthly thereafter
- Females Not of Child-Bearing Potential are not required to complete this survey

Males

- Males are not required to complete this survey

Prescribers

- Prescribers are required to complete one mandatory confidential prescriber survey initially and monthly thereafter.

Prescriber Requirements for Prescriptions

- The prescriber must send the prescription to a Reddy-Lenalidomide RMP Program or Reddy-Pomalidomide RMP Program registered pharmacy. To locate a registered pharmacy, please visit the RMP Program website at **www.reddy2assist.com** or call **1-877-938-0670**

- Prescribe no more than 4 weeks (28 days) of therapy, with no refills for females of child-bearing potential. Note: max 84 days can be prescribed for all other patients - males, females not of child-bearing potential.

- Prescribers must have completed the mandatory confidential prescriber survey either by phone or online initially and then monthly thereafter.

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

After the Last Dose of Treatment

After patients have stopped taking Reddy-Lenalidomide or Reddy-Pomalidomide, they must do the following:

ALL PATIENTS

- Must not donate blood for 4 weeks after treatment completion
- Must not share Reddy-Lenalidomide capsules or Reddy-Pomalidomide capsules—especially with females of reproductive potential
- Must return any unused Reddy-Lenalidomide capsules or Reddy-Pomalidomide capsules for disposal to the respective pharmacy that dispensed the capsules.
- Patients must be re-enrolled in the Reddy-Lenalidomide RMP program or Reddy-Pomalidomide RMP program if Reddy-Lenalidomide or Reddy-Pomalidomide is required and previous therapy has been discontinued. The program requirements should be met every time a patient starts a new course of treatment following discontinuation.

FEMALE PATIENTS OF CHILD-BEARING POTENTIAL

- Must not get pregnant for at least 4 weeks after stopping Reddy-Lenalidomide or Reddy-Pomalidomide by using at the same time, 2 effective methods of contraception (at least one highly effective method and one effective method) each time they engage in sexual activity with a male

MALE PATIENTS

- Must use a latex or synthetic condom each time they engage in sexual activity with females of child-bearing potential and for 4 weeks after stopping Reddy-Lenalidomide or Reddy-Pomalidomide, even if they have undergone a successful vasectomy
- Must not donate sperm during treatment, during dose interruption and for 4 weeks after stopping Reddy-Lenalidomide or Reddy-Pomalidomide

Adverse Event Reporting

REPORTING TO REDDY-LENALIDOMIDE RMP PROGRAM AND REDDY-POMALIDOMIDE RMP PROGRAM CONTACT CENTRE

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

If the patient mentions adverse events that are suspected to be associated with the use of Reddy-Lenalidomide or Reddy-Pomalidomide and/or any suspected pregnancy occurring during the treatment with Reddy-Lenalidomide or Reddy-Pomalidomide, report these experiences to Health Canada by:

A. 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.

B. 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 Contact Center 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.