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: Patient Guide

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

Reddy-Lenalidomide and Reddy-Pomalidomide can cause serious harm to an unborn baby such as birth defects and death. These products must not be given to a female who can become pregnant, is pregnant or is breastfeeding, unless it is through their respective RMP programs.

Reddy-Lenalidomide and Reddy-Pomalidomide are marketed only under controlled distribution programs. This is a requirement by Health Canada for Reddy-Lenalidomide and Reddy-Pomalidomide to prevent exposure to these products in unborn babies, as well as to inform prescribers, patients, and pharmacists on the serious risks and safe-use conditions for these medications. 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).

Patient Risk Category

Before prescribing Reddy-Lenalidomide or Reddy-Pomalidomide, your prescriber will determine your risk category and counsel you accordingly:

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 who have had a hysterectomy, who have had a bilateral oophorectomy, females with XY genotype, who have Turner syndrome, uterine agenesis, premature ovarian failure confirmed by a gynaecologist and prepubertal patients
who have not started menstruating

***Note:** *(For patients less than 19 years old)* - If they have not reached puberty or menses, they must notify the RMP Contact Centre 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 program based on the reclassification

3. Male Patients

Safety Measures

For all patients

• Your treatment 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

• Your treatment medication must be kept out of the reach of children and pets

• Do not open or unnecessarily handle the capsules. You must maintain the product in its original packaging until ingested and you must wash (with soap and water) any affected areas which may come into direct contact with non-intact capsules and/or its contents. If you are being assisted with your medication, women who are pregnant or that can get pregnant must wear latex gloves when handling the medication

• Do not donate blood during treatment, during breaks (dose interruptions), and for 4 weeks after stopping treatment

• Unused capsules should be returned for disposal to the pharmacy that dispensed the medication

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 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 7-14 days and 24 hours before being prescribed the medication for the first time, weekly for the first 4 weeks of treatment, then every 4 weeks during the rest of the treatment if regular or no menstrual periods, or every 2 weeks if your menstrual cycle is irregular. A pregnancy test should also be conducted 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 Pharmacy must dispense your medication within 7 days of your last negative pregnancy test. If the medication is not dispensed within 7 days, another pregnancy test will be required.

4. You will be required to fill a mandatory survey before you receive your first supply of the medication and before every subsequent prescription. The survey aims to ensure you understand the serious risks and safe use of the Product.

You can access the mandatory confidential patient survey online at **www.reddy2assist.com** or you can call **1-877-938-0670** for further assistance.

5. Stop taking the Product immediately and contact your prescriber and dispensing pharmacy if you become pregnant, miss a menstrual period or experience unusual bleeding, stop using contraception, or think for any reason you may be pregnant. If you are unable to contact your prescriber or pharmacist, call the RMP Program Contact Centre at **1-877-938-0670**

For Males

1. The Product is present in the semen of male patients who take this drug

2. You must never have unprotected sexual contact with a female who is or can become pregnant. An unborn baby may develop birth defects and may even die if exposed to the medication through your semen.

3. Inform your female partner that you are taking the Product and of the risks associated with it.

4. Always use a latex or synthetic condom every time you have sexual contact with a female who can become pregnant and that, while taking the drug, during dose interruptions and for 4 weeks after stopping treatment

OR

Completely abstain from sexual contact with females who are or can become pregnant while taking the medication, during dose interruptions and for 4 weeks after stopping treatment

5. Your female partner should use another method of contraception for extra protection

6. You must not donate sperm or blood during treatment, during dose interruptions, and for 4 weeks after stopping treatment

If you have unprotected sexual contact with a female who is or can become pregnant, or if you think for any reason that your female partner may be pregnant, contact your prescriber and dispensing pharmacy

• Take the Product exactly as prescribed and follow all requirements of the RMP program

• Talk to your healthcare provider if you experience any problems while taking the Product

How to Receive Prescriptions for the Product

Initial Prescription:

1. Enroll in the RMP Program

• You and your healthcare provider will complete and submit the Informed Consent Form which can be found through the RMP Program website (**www.reddy2assist.com**) or call **1-877-938-0670** for further assistance. Upon submitted the Informed Consent Form, you will be given a unique patient ID number

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.

3. Get Pregnancy tests (Females of child-bearing potential only)
• **Pregnancy Test #1**: If you can get pregnant, you must take an initial pregnancy test within 7-14 days of receiving a prescription

• **Pregnancy Test #2:** If you can get pregnant, you must take a second pregnancy test 24 hours prior to receiving a prescription

4. Complete your Mandatory Confidential Survey (Females of child-bearing potential only)

i. Female patients of child-bearing potential must complete surveys initially and monthly thereafter in order to obtain subsequent prescriptions. Female patients not of child-bearing potential and male patients are not required to complete the survey

5. Prescription
• Your healthcare provider will send your prescription to a registered pharmacy enrolled in the RMP Program.

6. Pharmacy
• A program trained pharmacist will counsel you every time if you are male or female of childbearing potential when you receive a supply of medication, either in person at the pharmacy or over the phone.

• They will also coordinate delivery of the Product to you directly or via shipment. If you are classified as female of child-bearing potential, you must pick up your prescription as soon as possible after your prescriber has sent it to the pharmacy

7. Receive the Product
• The Product will be dispensed/shipped with a Patient Medication Information to you or to the address you provide.
• A signature will be required upon pickup of this medication/to receive this shipment

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)
• Every 4 weeks if regular or no menstrual periods
• Every 2 weeks if menstrual periods are irregular

4. Complete your monthly Mandatory Confidential Survey (Females of child-bearing potential only)

5. Prescription
• Your healthcare provider will send your prescription to a registered pharmacy enrolled in the RMP Program.

6. Pharmacy

• A program trained pharmacist will counsel you every time if you are male or female of childbearing potential when you receive a supply of medication, either in person at the pharmacy or over the phone. They will coordinate delivery of the Product to you directly or via shipment. If you are classified as female of child-bearing potential, you must pick up your prescription as soon as possible after your prescriber has sent it to the pharmacy.

7. Receive the Product

• The Product will be dispensed/shipped with a Patient Medication Information to you or to the address you provide
• A signature will be required upon pickup of this medication/to receive this shipment

Restarting therapy after discontinuation:
You must be re-enrolled in the RMP program if the Product 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 two negative pregnancy tests (for females of child-bearing potential) before starting therapy

Important Information for Females of Child-Bearing Potential

Before taking the Product

• You must understand and provide Informed Consent agreeing that the Product should not be used during pregnancy as it may cause serious birth defects. You must agree that you will not take the Product 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 at least 1 highly effective method and at least 1 additional effective method of birth control every time you have sex with a male starting at least 4 weeks before taking treatment, during treatment, during dose interruptions and 4 weeks after stopping treatment, or completely abstain from heterosexual sexual contact.

• Your healthcare provider must give you a pregnancy test 7 to 14 days before you receive your first prescription for the Product, and again within 24 hours before you receive your first prescription for the Product. If you are pregnant, you cannot take the Product.

• You will have pregnancy tests before starting the Product and while taking the Product, even if you agree not to have sex with males

• Before starting the Product, you must complete an Informed Consent Form with your healthcare provider and you must take part in a mandatory confidential patient survey initially and monthly thereafter.

The survey will make sure that you receive, understand, and can follow information designed to prevent serious risks to unborn babies. You can access the mandatory confidential patient survey online at **www.reddy2assist.com** or you can call **1-877-938-0670** for further assistance.

• Your healthcare provider will talk with you about your birth control options

• Choose at least 1 highly effective method and at least 1 additional effective method of birth control

Talk to your healthcare provider about the following acceptable birth control methods. The effective methods of birth control that may be used at the same time can be found below

• Use **2 methods** of birth control at the same time (one highly effective method and one additional method simultaneously

Highly effective birth control methods*	PLUS	Additional effective birth control
• 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.*

• Remember: You must use at the same time at least 1 highly effective method and at least 1 additional effective method of birth control every time you have sex with a male. However, your healthcare provider may recommend that you use 2 different methods instead for medical reasons

• 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 the Product

• If you are able to get pregnant, you must continue (including during breaks [dose interruptions]) to use at the same time at least 1 highly effective method and at least 1 additional effective method 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:

1. Every week during the first 4 weeks of treatment; then,

2. Every 4 weeks if you do not have a menstrual periods or if your menstrual cycles are regular, or every 2 weeks if your cycles are irregular

3. If you miss your period or have unusual menstrual bleeding

• If you had sex with a male without using birth control or if you believe your birth control has failed, stop taking the Product immediately and call your healthcare provider right away. Your healthcare provider will discuss your options, which may include emergency birth control. Do not wait until your next appointment to tell your healthcare provider if you miss your menstrual period or if you think you may be pregnant

• If you get pregnant, or think you may be pregnant, you must immediately stop taking the Product. 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. If your healthcare provider is not available, call the RMP Program Contact Centre at **1-877-938-0670** for information on emergency contraception

• You must not breastfeed if you are taking the Product

• To continue receiving the Product, you must take part in a mandatory confidential patient survey every month. To take the survey, please go to **www.reddy2assist.com**, or call the RMP Program Contact Centre for assistance at **1-877-938-0670**

After stopping the Product

• You must continue to use at least 1 highly effective method and at least 1 additional effective method of birth control at the same time whenever you have sex with a male:

1. For at least 4 weeks after stopping the Product, or

2. Do not have any sex with a male for 4 weeks after stopping the Product

• Do not donate blood for at least 4 weeks after stopping the Product

Important Information for Females Not of Child-Bearing Potential

Before taking the Product

• You must understand and provide Informed Consent and confirm that you are not able to get pregnant because:

1. You have been in natural menopause for at least 12 months (excluding amenorrhea following cancer therapy), had a hysterectomy, and/or had bilateral oophorectomy

or

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

• For females who have not started their period (menstruation) and/or are under the age of 19, a parent or legal guardian must read the Informed Consent Form that says the patient is not pregnant, is not able to get pregnant, and/or will not be having sex with a male for at least 4 weeks before starting the Product, during therapy, and for at least 4 weeks after stopping the Product. If you have not reached puberty or menses, you must notify your healthcare provider and the RMP Contact Centre at **1-877-938-0670**, or through the RMP Program website (**www.reddy2assist.com**) when such change occurs and follow the requirements of the program based on the reclassification

While taking the Product
• Do not donate blood while you are taking the Product or during breaks (dose interruptions)

After Stopping the Product
• Do not donate blood for at least 4 weeks after stopping the Product

Important Information for Males

Before taking the Product

You must understand and provide Informed Consent. You must agree that while taking the Product, you will use a latex or synthetic condom **every time** you have sex with a female who is pregnant or who is able to get pregnant while taking treatment, during interruptions of treatment and for 4 weeks after stopping treatment. This must be done even if you have undergone a successful vasectomy.

• You must inform your sexual partner who can get pregnant that you are taking the Product and there is a risk of birth defects, stillbirths, and spontaneous abortion if a fetus is exposed to your sperm. Therefore, you must use a condom
• You must contact your doctor immediately if you think your female partners becomes pregnant while you are taking the Product

While taking the Product

• You must use a latex or synthetic 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)

• Your female partner should use another method of contraception for additional protection

• **Remember, not having sex is the only birth control method that is 100% effective**

• You must tell your healthcare provider right away if you have sex with a female without using a latex or synthetic condom or if you think for any reason that your partner is or may be pregnant. If for some reason your healthcare provider is not available, you can also contact the RMP Program Contact Centre for assistance at 1-877-938-0670
• You must not donate sperm while taking the Product, during breaks (dose interruptions) and for 4 weeks after stopping the Product

After stopping the Product

• For 4 weeks after receiving your last dose of the Product, you must use a latex or synthetic 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)

• You must not donate sperm or blood for 4 weeks after stopping the Product.

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 you experience side effects while taking Reddy-Lenalidomide or Reddy-Pomalidomide, you can report them to Health Canada
by:

A. Visiting the Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhpmps/medeff/reportdeclaration/index-eng.php) for information on how to report online, by mail or by fax

B. Or calling toll-free at 1-866-234-2345.

For more information about Reddy-Lenalidomide and Reddy-Pomalidomide and their respective Risk Management Programs, please visit www.reddy2assist.com or call the Contact Centre 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 Patient Medication Information, enclosed.