

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

## Reddy-Lenalidomide RMP Program: Patient 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.

### About the Reddy-Lenalidomide RMP Program:

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

Reddy-Lenalidomide is marketed only under a controlled distribution program. This is a requirement by Health Canada for Reddy-Lenalidomide to prevent exposure to Reddy-Lenalidomide in unborn babies, as well as to inform prescribers, patients, and pharmacists on the serious risks and safe-use conditions for Reddy-Lenalidomide. Only certified prescribers and pharmacies in the Reddy-Lenalidomide RMP program can prescribe or dispense this medication. In order to receive Reddy-Lenalidomide, all patients must be enrolled in the Reddy-Lenalidomide RMP program and agree to comply with the requirements of the program.

Information about Reddy-Lenalidomide and the Reddy-Lenalidomide RMP Program can be obtained by visiting the Reddy-Lenalidomide RMP Contact Centre at **1800 XXX XXX**, or through the Reddy-Lenalidomide RMP Program website ([www.Reddy2Assist.au](http://www.Reddy2Assist.au)).

### Patient Risk Category

Before prescribing Reddy-Lenalidomide, 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 Reddy-Lenalidomide RMP Contact Centre at **1800 XXX XXX**, or through the Reddy-Lenalidomide RMP Program website ([www.Reddy2Assist.au](http://www.Reddy2Assist.au)) 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

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

### 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 Reddy-Lenalidomide.  
You can access the mandatory confidential patient survey online at [www.Reddy2Assist.au](http://www.Reddy2Assist.au) or you can call **1800 XXX XXX** for further assistance.
5. Stop taking Reddy-Lenalidomide 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 Reddy-Lenalidomide RMP Program Contact Centre at **1800 XXX XXX**

#### **For Males**

1. Reddy-Lenalidomide is present in the semen of male patients who take this medication
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 Reddy-Lenalidomide and of the risks associated with this medication.
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 Reddy-Lenalidomide

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

## How to Receive Prescriptions for Reddy-Lenalidomide

### Initial Prescription:

1. Enroll in the Reddy-Lenalidomide RMP Program
  - You and your healthcare provider will complete and submit the Reddy-Lenalidomide Informed Consent Form which can be found through the Reddy-Lenalidomide RMP Program website ([www.reddy2assist.com](http://www.reddy2assist.com)) or call **1800 XXX XXX** 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 Reddy-Lenalidomide prescription
  - **Pregnancy Test #2:** If you can get pregnant, you must take a second pregnancy test 24 hours prior to receiving a Reddy-Lenalidomide 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 certified pharmacy enrolled in the Reddy-Lenalidomide RMP Program.
6. Pharmacy
  - The certified pharmacist will counsel you every time you receive a supply of medication, either in person at the pharmacy or over the phone.
  - They will also coordinate delivery of Reddy-Lenalidomide 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 Reddy-Lenalidomide
  - Reddy-Lenalidomide will be dispensed/shipped with a Medication Guide 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 certified pharmacy enrolled in the Reddy-Lenalidomide RMP Program.
  6. Pharmacy
    - The certified pharmacist will counsel you every time you receive a supply of medication, either in person at the pharmacy or over the phone. They will coordinate delivery of Reddy-Lenalidomide 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 Reddy-Lenalidomide
    - Reddy-Lenalidomide will be dispensed/shipped with a Medication Guide 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:**

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

## **Important Information for Females of Child-Bearing Potential**

### **Before taking Reddy-Lenalidomide**

- You must fill and sign the Informed Consent Form that says you understand that Reddy-Lenalidomide should not be used during pregnancy as it may cause serious birth defects. You must agree that you will not take Reddy-Lenalidomide if you are pregnant, become pregnant during treatment or during breastfeeding
- If there is any chance that you can get pregnant, you must agree to use at the same time 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 Reddy-Lenalidomide, 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 Reddy-Lenalidomide, and again within 24 hours before you receive your first prescription for Reddy-Lenalidomide. If you are pregnant, you cannot take Reddy-Lenalidomide
- You will have pregnancy tests before starting Reddy-Lenalidomide and while taking Reddy-Lenalidomide, even if you agree not to have sex with males
- Before starting Reddy-Lenalidomide, you must fill out 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.au](http://www.Reddy2Assist.au) or you can call **1800 XXX XXX** 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
<ul style="list-style-type: none"> <li>• Intrauterine device (IUD)</li> <li>• Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants)*</li> <li>• Tubal ligation (having your tubes tied)</li> <li>• Partner's vasectomy (tying of the tubes to prevent the passing of sperm)</li> </ul>	+	<ul style="list-style-type: none"> <li>• Male latex or synthetic condom</li> <li>• Diaphragm</li> <li>• Cervical cap</li> </ul>
Unacceptable forms of contraception		
<ul style="list-style-type: none"> <li>• Progesterone-only "mini-pills,"</li> <li>• IUD Progesterone T,</li> <li>• Female condoms,</li> <li>• Natural family planning (rhythm method) or breastfeeding,</li> <li>• Fertility awareness,</li> <li>• Withdrawal,</li> <li>• Cervical shield (a cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception)</li> </ul>		

*\*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 Reddy-Lenalidomide

- 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 Reddy-Lenalidomide 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 Reddy-Lenalidomide. 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 Reddy-Lenalidomide RMP Program Contact Centre at **1800 XXX XXX** for information on emergency contraception
- You must not breastfeed if you are taking Reddy-Lenalidomide
- To continue receiving Reddy-Lenalidomide, you must take part in a mandatory confidential patient survey every month. To take the survey, please go to [www.reddy2assist.com](http://www.reddy2assist.com), or call the Reddy-Lenalidomide RMP Program Contact Centre for assistance at **1800 XXX XXX**

## After stopping Reddy-Lenalidomide

- 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 Reddy-Lenalidomide, or
  2. Do not have any sex with a male for 4 weeks after stopping Reddy-Lenalidomide
- Do not donate blood for at least 4 weeks after stopping Reddy-Lenalidomide

## Important Information for Females Not of Child-Bearing Potential

### Before taking Reddy-Lenalidomide

- You must sign the Reddy-Lenalidomide Informed Consent Form 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 Reddy-Lenalidomide, during therapy, and for at least 4 weeks after stopping therapy. If you have not reached puberty or menses, you must notify your healthcare provider and the Reddy-Lenalidomide RMP Contact Centre at **1800 XXX XXX**, or through the Reddy-Lenalidomide RMP Program website ([www.reddy2assist.com](http://www.reddy2assist.com)) when such change occurs and follow the requirements of the program based on the reclassification

## While taking Reddy-Lenalidomide

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

## After Stopping Reddy-Lenalidomide

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

## Important Information for Males

### Before taking Reddy-Lenalidomide

You must sign the Reddy-Lenalidomide Informed Consent Form. You must agree that while taking Reddy-Lenalidomide, 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 Reddy-Lenalidomide. 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 Reddy-Lenalidomide 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 Reddy-Lenalidomide

## While taking Reddy-Lenalidomide

- 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 Reddy-Lenalidomide RMP Program Contact Centre for assistance at 1800 XXX XXX
- You must not donate sperm while taking Reddy-Lenalidomide (including during breaks [dose interruptions]) while taking Reddy-Lenalidomide and for 4 weeks after stopping Reddy-Lenalidomide

### **After stopping Reddy-Lenalidomide**

- For 4 weeks after receiving your last dose of Reddy-Lenalidomide, 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 Reddy-Lenalidomide

## **Adverse Event Reporting**

### **REPORTING TO REDDY-LENALIDOMIDE RMP PROGRAM CONTACT CENTRE**

Dr Reddy's Australia,  
Suite 3.03 Level 3, 390 St Kilda Road,  
Melbourne, VIC 3004  
Phone: 1800 XXX XXX  
Fax: 1800 XXX XXX  
Email: [Reddy2Assist.au@drreddys.com](mailto:Reddy2Assist.au@drreddys.com)  
Website: [www.Reddy2Assist.au](http://www.Reddy2Assist.au)

## **REPORTING TO HEALTH CANADA**

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

- A. Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhpmpps/medeff/report-declaration/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 the Reddy-Lenalidomide RMP Program, please visit [www.Reddy2Assist.au](http://www.Reddy2Assist.au) or call the Reddy-Lenalidomide RMP Program Contact Centre for assistance at 1800 XXX XXX.

**Reddy-Lenalidomide is only available through the Reddy-Lenalidomide RMP Program, a restricted distribution program.**

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

### **Confidentiality Statement**

The information in this document is confidential and the property of Dr. Reddy's Laboratories Australia Pty Ltd. No part of it may be transmitted, reproduced, published or used by any person/s without prior written authorisation from Dr. Reddy's Laboratories Australia Pty Ltd.

This Patient Guide is downloaded from [www.Reddy2Assist.au](http://www.Reddy2Assist.au), where more information about Reddy-Lenalidomide (lenalidomide) and the Reddy-Lenalidomide (lenalidomide) RMP Program can be found.