

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: Counselling Tool for Pharmacist**

**DO NOT RELEASE REDDY-LENALIDOMIDE OR REDDY-POMALIDOMIDE TO A PATIENT WITHOUT A VALID PRESCRIPTION AND CONFIRMATION NUMBER FROM THE REDDY-LENALIDOMIDE RMP PROGRAM AND REDDY-POMALIDOMIDE RMP PROGRAM.**

In addition to standard pharmacy practice counselling, male patients and female patients of childbearing potential taking Reddy-Lenalidomide or Reddy-Pomalidomide should be counselled by a Program trained pharmacist, at every dispense, on the key safety messages specific to their risk category.

Before you fill a prescription, confirm the patient's risk category. The patient's risk category can be verified online at [www.reddy2assist.com](http://www.reddy2assist.com) or by calling the respective RMP Program contact centers for assistance at 1-877-938-0670.

### **Checklist for female patients of child-bearing potential who should be counseled at every dispense:**

- Ensure that the patients are aware that they will receive the respective Patient Medication Information along with their respective prescription of Reddy-Lenalidomide or Reddy-Pomalidomide.

### **I counseled the patient on the following:**

- Must not take the medication if pregnant or breastfeeding. Must understand that any unborn baby may develop birth defects and may even die if exposed to the medication.
- **Must have a consultation on contraceptive options with a healthcare professional experienced in the use of contraceptive methods to discuss the best and most effective two simultaneous contraceptive methods to be used (applicable to every new patient who is a Female of Child-Bearing Potential)**
- Must use two 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 beginning at least 4 weeks before starting Reddy-Lenalidomide or Reddy-Pomalidomide, while taking Reddy-Lenalidomide or Reddy-Pomalidomide, during dose interruptions, and for at least 4 weeks after stopping Reddy-Lenalidomide or Reddy-Pomalidomide, OR completely abstaining from sex with a male. This applies to all female patients of child-bearing potential, including those who have amenorrhea, and those who do not normally use contraception due to a history of infertility.
- Highly effective methods of birth control may include: tubal ligation, IUD, hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants), or partner's vasectomy - and

additional effective methods of birth control may include: male latex or synthetic condom, diaphragm, or cervical cap.

- Unacceptable methods of birth control are progesterone-only “mini-pills,” IUD Progesterone T, female condoms, natural family planning (rhythm method) or breastfeeding, fertility awareness, withdrawal, and cervical shield (a cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception). The patient understands the cumulative risks of deep venous thrombosis, including, but not limited to, Lenalidomide or pomalidomide, dexamethasone, cancer and hormonal contraception.
- Must understand the risk of possible contraceptive failure and the potential need for emergency contraception.
- Must obtain a pregnancy test—performed by their healthcare provider—Must have two negative pregnancy tests before starting treatment; the first test should be conducted 7 to 14 days prior to starting treatment and the second test within 24 hours before starting treatment. Then a pregnancy test should be conducted once weekly during the first 4 weeks of use and must be negative each time. Thereafter, pregnancy testing should be repeated and must be negative every 4 weeks during the rest of their treatment and during treatment interruption in females with regular or no menstrual periods. If menstrual periods are irregular, the pregnancy testing should occur every 2 weeks. A final pregnancy test should be performed 4 weeks after stopping treatment.
- Must understand that pregnancy tests are required even if the patient has not had a menstrual period due to treatment of their disease.
- Must immediately stop taking Reddy-Lenalidomide or Reddy-Pomalidomide and inform their prescriber and dispensing pharmacy in the event of becoming pregnant while taking the drug, or if the patient misses a menstrual period, experience unusual bleeding, stop using contraception or think for any reason they may be pregnant. If unable to contact their prescriber or dispensing pharmacist, the respective RMP Program contact centers should be notified by calling: 1-877-938-0670
- Must read and understand the contents of the Patient Medication Information, including the risks and possible side effects of the medication.
- Possible side effects include neutropenia, thrombocytopenia, deep vein thrombosis, pulmonary embolism, myocardial infarction, cerebrovascular events, liver problems, and anaphylaxis
- Must never share Reddy-Lenalidomide capsules or Reddy-Pomalidomide capsules with anyone else—especially with females who can get pregnant, even if the person has similar symptoms. Also, the medication must be kept out of reach of children.
- Must inform caregivers assisting with the patient’s medication, who are or can become pregnant, that they must wear latex gloves.
- Must never donate blood while taking Reddy-Lenalidomide or Reddy-Pomalidomide (including dose interruptions) and for 4 weeks after stopping Reddy-Lenalidomide or Reddy-Pomalidomide
- Must not extensively handle or open Reddy-Lenalidomide capsules or Reddy-Pomalidomide capsules. The medication should be kept in its original packaging until ingested and any area that comes into direct contact with non-intact capsules must be washed using soap and water. Latex gloves must be worn while handling Reddy-Lenalidomide or Reddy-Pomalidomide
- Must not break, chew, or open Reddy-Lenalidomide capsules or Reddy-Pomalidomide capsules
- Must return any unused capsules to the dispensing pharmacy for proper disposal.
- Instructions on Reddy-Lenalidomide or Reddy-Pomalidomide dose and administration

Strength of capsules (mg):

Number of Capsules dispensed:

**Female Children (< 18 years of age):**

- Parent of legal guardian must have read the Reddy-Lenalidomide RMP program or Reddy-Pomalidomide RMP Program education material and agreed to ensure compliance

**Checklist for female patients not of child-bearing potential:**

- Ensure that the patients are aware that they will receive the respective Patient Medication Information along with their respective prescription of Reddy-Lenalidomide or Reddy-Pomalidomide.

**I counseled the patient on the following:**

- Must understand that any unborn baby may develop birth defects and may even die is exposed to the medication.
- Must read and understand the contents of the Patient Medication Information, including the risks and possible side effects of the medication.
- Possible side effects include neutropenia, thrombocytopenia, deep vein thrombosis, pulmonary embolism, myocardial infarction, cerebrovascular events, liver problems, and anaphylaxis
- Must never share Reddy-Lenalidomide capsules or Reddy-Pomalidomide capsules with anyone else—especially with females who can get pregnant, even if the person has similar symptoms. Also, the medication must be kept out of reach of children.
- Must inform caregivers assisting with the patient's medication, who are or can become pregnant, that they must wear latex gloves.
- Must never donate blood while taking Reddy-Lenalidomide or Reddy-Pomalidomide (including dose interruptions) and for 4 weeks after stopping Reddy-Lenalidomide or Reddy-Pomalidomide
- Must not extensively handle or open Reddy-Lenalidomide capsules or Reddy-Pomalidomide capsules. The medication should be kept in its original packaging until ingested and any area that comes into direct contact with non-intact capsules must be washed using soap and water.
- Must not break, chew, or open Reddy-Lenalidomide capsules or Reddy-Pomalidomide capsules
- Must return any unused capsules to the dispensing pharmacy for proper disposal.
- Instructions on Reddy-Lenalidomide or Reddy-Pomalidomide dose and administration

Strength of capsules (mg):

Number of Capsules dispensed:

**Female Children (< 18 years of age):**

- Parent of legal guardian must have read the Reddy-Lenalidomide RMP Program or Reddy-Pomalidomide RMP Program education material and agreed to ensure compliance
- Parent or legal guardian must inform the child's healthcare provider when the child begins menses

**Checklist for male patients who should be counseled at every dispense:**

- Ensure that the patients are aware that they will receive the respective Patient Medication Information along with their respective prescription of Reddy-Lenalidomide or Reddy-Pomalidomide

**I counseled the patient on the following:**

- Must understand that any unborn baby may develop birth defects and may even die if exposed to the medication through semen
- Must never have unprotected sexual contact with a female who is or can become pregnant.
- Must use a latex or synthetic condom every time when engaging in sexual intercourse with a female who is or can get pregnant, while taking the medication, during dose interruption and for 4 weeks after stopping treatment OR completely abstain from sexual contact with females who are pregnant or can become pregnant. This applies even if the patient has had a successful vasectomy
- Must inform their sexual partner who is pregnant or can become pregnant that they are taking the medication, potential risk of birth defects, stillbirths and spontaneous abortions if a developing fetus is exposed to the semen of the male patient and that they must use a latex or synthetic condom. In addition, the patient's female partner should also use another method of contraception for extra protection.
- Must inform their prescriber and dispensing pharmacy if they have unprotected sexual contact with a female who is or can become pregnant or if they think for any reason their partner may be pregnant. If unable to contact their prescriber or dispensing pharmacist, the respective RMP Program contact centers should be notified by calling: 1-877-938-0670
- Must read and understand the contents of the Patient Medication Information, including the risks and possible side effects of the medication.
- Possible side effects include neutropenia, thrombocytopenia, deep vein thrombosis, pulmonary embolism, myocardial infarction, cerebrovascular events, liver problems, and anaphylaxis
- Must never share Reddy-Lenalidomide capsules or Reddy-Pomalidomide capsules with anyone else—especially with females who can get pregnant, even if the person has similar symptoms. Also, the medication must be kept out of reach of children.
- Must inform caregivers assisting with the patient's medication, who are or can become pregnant, that they must wear latex gloves.
- Must never donate blood or sperm while taking Reddy-Lenalidomide or Reddy-Pomalidomide (including dose interruptions) and for 4 weeks after stopping Reddy-Lenalidomide or Reddy-Pomalidomide
- Must not extensively handle or open Reddy-Lenalidomide capsules or Reddy-Pomalidomide capsules. The medication should be kept in its original packaging until ingested and any area that comes into direct contact with non-intact capsules must be washed using soap and water.
- Must not break, chew, or open Reddy-Lenalidomide capsules or Reddy-Pomalidomide capsules
- Must return any unused capsules to the dispensing pharmacy for proper disposal.
- Instructions on Reddy-Lenalidomide or Reddy-Pomalidomide dose and administration

Strength of capsules (mg):

Number of Capsules dispensed:

**Male Children (< 18 years of age):**

- Parent of legal guardian must have read the Reddy-Lenalidomide RMP Program or Reddy-Pomalidomide RMP Program education material and agreed to ensure compliance



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This Counselling Tool for Pharmacist is downloaded from [www.reddy2assist.com](http://www.reddy2assist.com), where more information about Reddy-Lenalidomide (lenalidomide) and Reddy-Pomalidomide (pomalidomide) and their respective Risk Management Programs can be found.