



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.

## Attention for Healthcare Providers of Females Who Can Get Pregnant:

This letter is for healthcare providers regarding different types of birth control options available for the patient.

Dear Healthcare Provider,

The patient is being treated with Reddy-Lenalidomide or Reddy-Pomalidomide. Due to their structural similarity to thalidomide, a known teratogen, Reddy-Lenalidomide and Reddy-Pomalidomide are only available under a controlled distribution program: the Reddy-Lenalidomide RMP Program for Reddy-Lenalidomide and the Reddy-Pomalidomide RMP Program for Reddy-Pomalidomide.

The goals of the Reddy-Lenalidomide RMP Program and Reddy-Pomalidomide RMP Program are:

1. To prevent the risk of embryo-fetal exposure to Reddy-Lenalidomide and Reddy-Pomalidomide.
2. To inform prescribers, patients, and pharmacists on the serious risks and safe-use conditions for Reddy-Lenalidomide and Reddy-Pomalidomide.

To enroll in the Reddy-Lenalidomide RMP Program or Reddy-Pomalidomide RMP Program, the patient, with the knowledge of the healthcare provider who prescribed Reddy-Lenalidomide or Reddy-Pomalidomide, agreed to follow the program's contraception requirements while on Reddy-Lenalidomide therapy or Reddy-Pomalidomide therapy. Unless she completely abstains from sexual intercourse with a male partner, she is required to use at least one highly effective birth control method and at least one additional effective method **at the same time**. 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. Please refer to the table below of the acceptable forms of contraception to help facilitate the discussion on contraception.

### Effective Methods of Birth Control Used at the Same Time

Highly effective birth control methods	PLUS	Additional effective birth control methods
<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		



- 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 contraception is medically contraindicated, 2 other contraceptive methods may be used simultaneously during periods of concomitant use and for 4 weeks after therapy with Reddy-Lenalidomide or Reddy-Pomalidomide ends. Instruct the patient to immediately stop taking Reddy-Lenalidomide or Reddy-Pomalidomide and contact her doctor, if she becomes pregnant while taking this drug, if she misses her menstrual period or experiences unusual menstrual bleeding, if she stops taking birth control or if she thinks FOR ANY REASON that she may be pregnant.

Advise patient that if her doctor is not available, she can call the RMP Program Contact Centre at 1-877-938-0670. There are other risks associated with Reddy-Lenalidomide treatment or Reddy-Pomalidomide treatment as described in their respective Prescribing Information. For respective Prescribing Information, including Boxed Warnings, or details about the Reddy-Lenalidomide RMP Program and Reddy-Pomalidomide RMP Program, please visit [www.reddy2assist.com](http://www.reddy2assist.com). You may contact the RMP Program Contact Centre at 1-877-938-0670 if you have any questions about the information contained in this letter or the safe and effective use of Reddy-Lenalidomide or Reddy-Pomalidomide.

Sincerely,

[Signature]

[place HCP name here]

[place title here]

For more information about Reddy-Lenalidomide and Reddy-Pomalidomide, and their respective Risk Management Plan, please visit our website or call Dr. Reddy's Laboratories Canada Inc. at 1-877-938-0670.

Return this form completed 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](mailto:reddy2assist@drreddys.com)**

**Website: [www.reddy2assist.com](http://www.reddy2assist.com)**



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This Healthcare Provider Letter 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 Program can be found.