



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

# Reddy-Pomalidomide RMP Program: Informed Consent Form

## For Patients Taking Reddy- Pomalidomide

DO NOT sign this form or take Reddy-Pomalidomide if there is any information about Reddy-Pomalidomide your doctor/pharmacist has given you that you do not understand.

For All Patients:

INITIAL

My doctor/pharmacist has provided me with verbal and written information about Reddy-Pomalidomide, and I understand the following:

Reddy-Pomalidomide may cause serious birth defects or death of an unborn baby and spontaneous abortion, therefore effective birth control must be used

- By all females of reproductive potential
- Males who engage in sexual intercourse with a female of reproductive potential

- To obtain my unique Patient ID number, I must complete this Informed Consent form and send to Dr. Reddy's Laboratories, Inc. 
  - Once registered, Reddy-Pomalidomide RMP Program will send me a Patient Guide with information on Reddy-Pomalidomide and its safe use

- I will be assigned correctly to one of the following patient risk categories by my physician:  
*Please initial appropriate box*

- **Female 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.

- **Female NOT of child-bearing potential:** females who have been in natural menopause for at least 12 consecutive months (excluding amenorrhea following cancer therapy), had a hysterectomy, and/or had bilateral oophorectomy. FNCNP also includes those with XY genotype, Turner's syndrome, uterine agenesis, or premature ovarian failure confirmed by a gynecologist

- **Male patient**

- I will have regular blood tests during my treatment with Reddy-Pomalidomide.

- I won't donate blood during treatment, during dose interruptions and for 4 weeks after stopping treatment

- I will not share Reddy-Pomalidomide with any other person and will keep out of reach of children/pets

- I will return all unused Reddy-Pomalidomide capsules to my pharmacist at the end of treatment

- I will not extensively handle or open the product, and will maintain the product in its original packaging until ingested. I will wash any affected areas which may come into direct contact with non-intact capsules or their contents using soap and water

- *(For patients less than 19 years old)* - If I have not reached puberty or menses, I will notify my healthcare provider and the Reddy-Pomalidomide RMP Contact Center at **1-877-938-0670**, or through the Reddy-Pomalidomide RMP Program website ([www.reddy2assist.com](http://www.reddy2assist.com)) when such change occurs and I will follow the requirements of the program based on the reclassification

For Female Patients of Child-Bearing Potential:	INITIAL
I have reviewed the information that my doctor/pharmacist has given me about pregnancy prevention and Reddy-Pomalidomide, and I understand the following:	
<ul style="list-style-type: none"> <li>• Reddy-Pomalidomide may cause serious birth defects or death of an unborn baby and spontaneous abortion</li> </ul>	<input type="checkbox"/>
<ul style="list-style-type: none"> <li>• I must not take Reddy-Pomalidomide if I am pregnant, become pregnant during treatment, or during breastfeeding</li> </ul>	<input type="checkbox"/>
<ul style="list-style-type: none"> <li>• I will need to undergo regular pregnancy tests: 7-14 days and 24 hours before being prescribed the medication for the first time. Every week during the first 4 weeks of treatment. During the rest of my treatment and during treatment interruption, pregnancy testing will be repeated every 4 weeks if I have regular menses or am amenorrheic (or every 2 weeks if my menses is irregular), and a final pregnancy test 4 weeks after stopping treatment</li> </ul>	<input type="checkbox"/>
<ul style="list-style-type: none"> <li>• I must immediately stop taking Reddy-Pomalidomide and inform my prescriber and pharmacist if:               <ul style="list-style-type: none"> <li>○ I become pregnant while taking the drug, I miss my menstrual period or experience unusual menstrual bleeding, I stop using contraception, or think I may be pregnant. If I am unable to contact my prescriber or pharmacist, I can call the Reddy-Pomalidomide RMP Program Contact Centre.</li> </ul> </li> </ul>	<input type="checkbox"/>
<ul style="list-style-type: none"> <li>• I must return to the doctor for scheduled pregnancy tests and to receive a new prescription</li> </ul>	<input type="checkbox"/>
<ul style="list-style-type: none"> <li>• I must use two effective birth control methods at the same time every time I have sex with a man, starting at least 4 weeks before starting Reddy-Pomalidomide, while taking the medication or during interruptions of treatment, and for 4 weeks after stopping treatment unless I completely abstain from heterosexual sexual contact.</li> </ul>	<input type="checkbox"/>
<ul style="list-style-type: none"> <li>• I understand that “effective birth control” means using one highly effective method and one additional method simultaneously. <i>See patient guide for examples</i></li> </ul>	<input type="checkbox"/>
<ul style="list-style-type: none"> <li>• I understand that birth control methods may fail and the potential need for emergency contraception and I know I can contact my healthcare provider for more information.</li> </ul>	<input type="checkbox"/>
<ul style="list-style-type: none"> <li>• I must complete a mandatory patient confidential survey before every prescription</li> </ul>	<input type="checkbox"/>

For Females Not of Child-Bearing Potential:	INITIAL
I have reviewed the information that my doctor/pharmacist has given me about pregnancy prevention and Reddy-Pomalidomide, and I confirm the following:	
<ul style="list-style-type: none"> <li>• I am not able to get pregnant because have been postmenopausal naturally for at least 12 months, (excluding amenorrhea cancer therapy), or I have had both my ovaries and/or uterus removed, or I am XY genotype, or I have Turner syndrome, or I have uterine agenesis or I have not yet reached puberty and have not started menstruating yet.</li> </ul>	<input type="checkbox"/>

For Male Patients Only:	INITIAL
I have reviewed the information that my doctor/pharmacist has given me about pregnancy prevention and Reddy-Pomalidomide, and I understand the following:	
<ul style="list-style-type: none"> <li>• Reddy-Pomalidomide is present in the sperm of males who take this drug. I must never have unprotected sexual contact with a female who is or can become pregnant.</li> </ul>	<input type="checkbox"/>
<ul style="list-style-type: none"> <li>• I must either completely abstain from sexual contact with females who are or can become pregnant or use a condom every time I have sexual intercourse with a woman who is pregnant or can get pregnant (even if I have undergone a successful vasectomy). I must use a condom while taking Reddy-Pomalidomide, during interruptions of treatment, and for 4 weeks after stopping treatment</li> </ul>	<input type="checkbox"/>



- I will inform my sexual partner who is or can get pregnant that I am taking Reddy-Pomalidomide and there is a risk of birth defects, stillbirths, and spontaneous abortions if a fetus is exposed to my sperm. Therefore, I must use a condom.
- I will not donate sperm while taking Reddy-Pomalidomide, during dose interruptions, and for 4 weeks after stopping Reddy-Pomalidomide
- I will contact my doctor and dispensing pharmacy if I have unprotected sexual contact with a female who is or can become pregnant while taking Reddy-Pomalidomide, or think for any reason that my sexual partner may be pregnant

I verify that the information provided is complete and accurate. I agree and consent to the collection, use and disclosure of my personal and medical information by the Program Administrator, and Reddy2Assist Program personnel ("Program Personnel"), for the purposes of determining my eligibility for the Program and conducting Program related activities.

I understand that I may withdraw my consent at any time by faxing a signed request to the Program Administrator at the fax number provided below, but if I do so, I understand that to the extent that such consent is necessary to provide the Program services, my participation in the Program may be terminated and, among other things, I may not be able to get help with reimbursement for my medication.

I understand that I may obtain a copy of my health information to correct errors, update information or direct questions to the Program Administrator during the subsistence of my consent, unless otherwise prohibited by law.

I understand that the Program Administrator may share health information that does not identify me with third parties even after I withdraw my consent.

- Using the contact information I have provided, I expressly consent for the Program Administrator and Program Personnel to contact me for the purposes of enrollment into the Program.
- I have provided my email address and expressly consent to electronic communications. I understand I can withdraw my consent to electronic communications at any time.

I acknowledge that my doctor/pharmacist has explained all of the above statements that are applicable to me, and I fully understand them. I also acknowledge that I may be contacted by a program representative to confirm my understanding of the program.

For patients <18 years of age, parent or legal guardian must read the Reddy-Pomalidomide RMP program education resources and agree to ensure compliance.

Indication for Reddy-Pomalidomide:

Patient Name:

Patient Phone Number:

Patient Address (for mailing Patient Guide):

Patient signature: \_\_\_\_\_ Date: \_\_\_\_\_

Patient's Caretaker/Guardian: \_\_\_\_\_ Date: \_\_\_\_\_

Physician/Pharmacist Name: \_\_\_\_\_

Physician/Pharmacist Phone Number: \_\_\_\_\_



Physician/Pharmacist signature: \_\_\_\_\_ Date: \_\_\_\_\_

A Patient Guide with information on Reddy-Pomalidomide and its safe use will be sent to you at the address indicated above.

For more information about Reddy-Pomalidomide and the Reddy-Pomalidomide RMP program, 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)**

**Keep a copy of this form for your records.**

#### **Confidentiality Statement**

The information in this document is confidential and the property of Dr. Reddy's Laboratories Canada Inc.

No part of it may be transmitted, reproduced, published or used by any person/s without prior written authorisation from Dr. Reddy's Laboratories Canada Inc.

This Informed Consent Form is downloaded from [www.reddy2assist.com](http://www.reddy2assist.com), where more information about Reddy-Pomalidomide (pomalidomide) and the Reddy-Pomalidomide (pomalidomide) RMP Program can be found.