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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.

Informed Consent Form

Before a patient can receive **Reddy-Lenalidomide** or **Reddy-Pomalidomide** (the "Product"), they must be enrolled in the RMP program for these products and agree to comply with its requirements as stipulated in this Informed Consent Form.

DO NOT give consent or take the Product if there is any information about the Product your doctor/pharmacist has given you that you do not understand.

For All Patients:

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

- The Product 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.
- I will have regular blood tests during my treatment with the Product.
- I won't donate blood during treatment, during dose interruptions and for 4 weeks after stopping treatment
- I will not share the Product with any other person and will keep out of reach of children/pets
- I will return all unused 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 RMP Contact Center at **1-877-938-0670**, or through website (**www.reddy2assist.com**) when such change occurs and I will follow the requirements of the program based on the reclassification
- I will be assigned correctly to one of the following patient risk categories by my physician:
  Choose 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**

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For Female Patients of Child-Bearing Potential:

I have reviewed the information that my doctor/pharmacist has given me about pregnancy prevention and the Product, and I understand the following:

- The Product may cause serious birth defects or death of an unborn baby and spontaneous abortion
- I must not take the Product if I am pregnant, become pregnant during treatment, or during breastfeeding
- 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
- I must immediately stop taking the Product and inform my prescriber and pharmacist if:
    - 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 RMP Program Contact Centre.
- I must return to the doctor for scheduled pregnancy tests and to receive a new prescription
- 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 the Product, while taking the medication or during interruptions of treatment, and for 4 weeks after stopping treatment unless I completely abstain from heterosexual sexual contact.
- I understand that “effective birth control” means using one highly effective method and one additional method simultaneously. *See patient guide for examples*
- 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.
- I must complete a mandatory patient confidential survey before every prescription

For Females Not of Child-Bearing Potential:

I have reviewed the information that my doctor/pharmacist has given me about pregnancy prevention and the Product, and I confirm the following:

- 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.

For Male Patients Only:

I have reviewed the information that my doctor/pharmacist has given me about pregnancy prevention and the Product, and I understand the following:

- The Product 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.
- 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 the Product, during interruptions of treatment, and for 4 weeks after stopping treatment

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- I will inform my sexual partner who is or can get pregnant that I am taking the product 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 the Product, during dose interruptions, and for 4 weeks after stopping the Product
- 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 the Product, 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 review and understand the RMP program education resources and agree to ensure compliance.

Indication:

Patient Name:

Patient Phone Number:

Patient Address (for mailing Patient Guide upon request by patient):

Consent:

☐ On Paper
☐ Online, email the consent form to Patient/ Patient's Caretaker/Guardian as applicable
☐ Verbal Consent (In case of verbal consent, the concerned physician/pharmacist shall provide his/her signature at the bottom of the consent form and by doing so agrees that all the relevant points have been reviewed and discussed with the patient or caretaker/guardian, as applicable and verbal consent has been provided by the concerned)

Patient signature (Not applicable if verbal consent provided):_____Date: _____

Patient's Caretaker/Guardian (Not applicable if verbal consent provided by patient's caretaker/guardian or the patient is capable of providing consent):_____ Date: _____

Physician/Pharmacist Name: _____

Physician/Pharmacist Phone Number: _____

Physician/Pharmacist signature: _____ Date: _____

The Patient Guide with information on the Product and its safe use, as well as the information about the RMP Program can be downloaded from www.reddy2assist.com or can be mailed upon request by patient.

Note: The consent procedure will be administered one time when you are enrolled in the program for the first time and will continue to be applicable if you switch the treatment (Lenalidomide or Pomalidomide)

For more information about Reddy- Lenalidomide and Reddy- Pomalidomide and their respective Risk Management Programs, please visit **www.reddy2assist.com** or call for assistance 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
Website: www.reddy2assist.com
Keep a copy of this form for your records.