

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: Pregnancy Report Form

Please complete this form to report an identified pregnancy exposure (whether the exposure was via the patient or partner) treated with Reddy-Lenalidomide or Reddy-Pomalidomide. Please send immediately to Dr. Reddy's Laboratories, Inc. Contact details are given below.

As part of the Reddy-Lenalidomide RMP Program and Reddy-Pomalidomide RMP Program, it is essential that we follow-up on all reported pregnancies. Dr. Reddy's will therefore be in contact with you for further information in due course and would value your cooperation to ensure we are able to obtain all relevant details on identified fetal exposure to Reddy-Lenalidomide or Reddy-Pomalidomide.

Adverse Event Reporting

REPORTING TO REDDY-LENALIDOMIDE RMP PROGRAM AND REDDY-POMALIDOMIDE RMP PROGRAM CONTACT CENTER:

Rx Infinity, 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

PREGNANCY REPORT FORM

REPORTER INFORMATION

Reporter Name: _____

Address: _____

Occupation: _____

Phone Number: _____

Email Address: _____

PATIENT EXPOSURE INFORMATION: Please fill out relevant section, as applicable

FEMALE PATIENT TAKING TREATMENT MEDICATION

Patient ID: _____

Date of Birth: _____

Age: _____

FEMALE PARTNER OF MALE PATIENT TAKING TREATMENT MEDICATION

Female Partner Date of Birth: _____

Female Partner Age: _____

Male Patient ID: _____

Male Patient Date of Birth: _____

Male Patient Age: _____

PATIENT TREATMENT INFORMATION:

Name of the treatment (select appropriate option):

☐ REDDY-LENALIDOMIDE CAPSULE

☐ REDDY-POMALIDOMIDE CAPSULE

Indication for Use: _____

Lot Number: _____ Expiry Date: _____ Dose: _____ Frequency: _____

Start Date: _____ Stop Date: _____

FOLLOW-UP OF THE PREGNANCY

	Yes	No
Has the patient already been referred to an Obstetrician/Gynecologist?		

If yes, please specify his/her name and contact details:

REASON FOR FAILURE OF PREGNANCY PREVENTION PROGRAM		
	Yes	No
Was patient erroneously considered not to be of child-bearing potential?		
If yes, state reason for considering not to be of child-bearing potential		
a. Age \geq 50 years and naturally amenorrheic for \geq 12 consecutive months (excluding amenorrhea following cancer therapy), had a hysterectomy, and/or had bilateral oophorectomy		
b. Premature ovarian failure confirmed by a specialist gynecologist		
c. XY genotype, Turner's syndrome, uterine agenesis.		
Indicate from the list below what contraception was used	Yes	No
a. Intrauterine device (IUD)		
b. Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants)		
c. Partner's vasectomy		
d. Tubal ligation		
e. Male latex or synthetic condom		
f. Diaphragm		
g. Cervical cap		
h. Progesterone-only "mini-pills"		
i. IUD Progesterone T		
j. Female condom		
k. Natural family		
l. Planning (rhythm method) or breastfeeding		
m. Fertility awareness		
n. Withdrawal		
o. Cervical shield		
p. None		
q. Other _____		
Indicate from the list below the reason for contraceptive failure	Yes	No
Missed oral contraception		
Other medication or intercurrent illness interacting with oral contraception		
Identified mishap with barrier method		
Unknown		
Did the patient commit to complete and continuous abstinence?		
Was Reddy-Lenalidomide or Reddy-Pomalidomide started despite patient already being pregnant?		
Did patient receive educational materials on the potential risk of teratogenicity?		
Did patient receive instructions on need to avoid pregnancy?		

PRENATAL INFORMATION						
Date of last menstrual period:	Estimated Delivery Date:			Pregnancy Termination Date:		
<u>Pregnancy test</u>	<u>Reference range</u>			<u>Date</u>		
Urine Qualitative						
Serum quantitative						
PAST OBSTRETRIC HISTORY						
	Outcome					
Year of pregnancy	Spontaneous abortion	Therapeutic abortion	Live birth	Still birth	Gestational Age	Type of delivery
BIRTH DEFECTS						
				Yes	No	Unknown
Was there any birth defect from any pregnancy?						
Is there any family history of congenital abnormality?						
If yes to either of these questions, please provide details below						

MATERNAL PAST MEDICAL HISTORY				
Condition	Dates		Treatment	Outcome
	From	To		
MATERNAL CURRENT MEDICAL CONDITIONS				
Condition	From	Treatment		
MATERNAL SOCIAL HISTORY				
			Yes	No
Alcohol				
If yes, amount/units per day:				

[illegible]



Any relevant information to include:

NAME OF PERSON COMPLETING THIS FORM	SIGNATURE	DATE

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 Pregnancy Report Form is downloaded from www.reddy2assist.com, where more information about Reddy-Lenalidomide (lenalidomide) and Reddy-Pomalidomide (pomalidomide), and their respective Risk Management Program can be found.