Lenalidomide Pregnancy Reporting Form

Australia

Complete this form to report pregnancy in a patient (or the patient's female partner) who is being treated with lenalidomide. Please send it to Cipla immediately. Contact details are provided below.

When implementing the Cipla safety monitoring system, it is important to monitor all reported cases of pregnancy. Therefore, Cipla will liaise with you to obtain further information. We will value your cooperation to ensure that we receive all relevant information on the effects of lenalidomide on the foetus.

Email: Lenalidomide.cipla@cipla.com

Date of Awareness:

INITIAL PREGNANCY NOTIFICATION FORM

INFORMATION ABOUT THE REPORTER	
Reporter name	Date:
Reporter's Contact Information/ Address:	Reporter's Signature:
E-Mail address:	Phone number.:
Fax Number:	
INFORMATION ABOUT THE FEMALE PATIENT/MALE PATIENT'S FEMALE PARTNER/ PATIENTS DETAILS	
Sex of Patient: ☐ Female ☐ Male	
☐ Pregnancy of Patient ☐ Pregnancy of Patient's Partner **OR** ☐ Exposure of a Pregnant Female (complete information below)	
Pregnant Woman's Initials (F, M, L):	Age: Date of birth:
Patient Initials (F, M, L): (Who received drug)	Age: Date of birth:
Drug Name:	
Date of First Dose:	Date of Last Dose:
Pregnancy Initially Diagnosed By:	
☐ Home Urine Test	
☐ Office Urine Test	
☐ Serum Test	
Date of Pregnancy Test: / / (DD/MMM/YY)	Last Menstrual Period: / / (DD/MMM/YY)
Female is Currently: ☐ weeks pregnant **OR** ☐ No longer Pregnant ☐ Unknown	
Female has Elected to: ☐ Carry Pregnancy to Term	Expected Date of Delivery: / / (DD/MMM/YY)
☐ Terminate Pregnancy	Date Performed or Pending: / / (DD/MMM/YY)

INFORMATION ABOUT MALE PATIENT (PREGNANCY OF FEMALE PARTNER)		
ID/Name:	Age:	Date of birth:

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PATIENT TREATMENT INFORMATION: LENALIDOMIDE			
Approved by TGA: November 2022 Lot no.	Expiration date:	Dose:	Frequency:
Date of start:		End date:	
Indications for use:			

FOLLOW – UP OF PREGNANCY	Yes	No
Has the patient already been referred to an obstetrician gynaecologist?		
If so, please provide his name and contact details:		

PATIENT'S PRESCRIBING PHYSICIAN'S INFORMATION:	
Physician's Name:	Date:
Physician's Contact Information/ Address:	Physician's Signature:
Physician's Phone number.:	Physician's E-Mail address:
Physician's Fax Number:	

PREGNANCY PREVENTION PROGRAM FAILURE REASON/ Background Information on Reason for Pregnancy	Yes	No
Was the patient erroneously considered of non-childbearing potential?	☐	☐
If yes, please state the reasons for considering non-childbearing potential.		
a. ≥ Age 50 years and naturally amenorrhoeic* for 1 year *amenorrhoea following cancer therapy or during breastfeeding does not rule out childbearing potential	☐	☐
b. Premature ovarian failure was confirmed by a specialist gynecologist	☐	☐
c. Previous bilateral salpingo-oophorectomy or hysterectomy.	☐	☐
d. XY genotype, Turner syndrome, uterine agenesis.	☐	☐

Indicate from the following table which method of contraception was used:	Yes	No
a. Implant	☐	☐
b. Levonorgestrel-releasing intrauterine system (IUS)	☐	☐
c. Medroxyprogesterone acetate depot injection	☐	☐
d. Tubal sterilization (specify below)	☐	☐
i. Tubal ligation	☐	☐
ii. Tubal diathermy	☐	☐
iii. Tubal clips	☐	☐
e. Sex with a vasectomized male partner only: Vasectomy must be confirmed by two negative sperm tests	☐	☐
f. Inhibition of ovulation with progesterone pills (i.e. desogestrel)	☐	☐
g. Other progesterone-only pills	☐	☐

h. Combined oral contraceptive pills	☐	☐
i. Other intra-uterine devices	☐	☐
j. Condoms	☐	☐
k. Cervical cap	☐	☐
l. Sponge	☐	☐
m. Withdrawal	☐	☐
n. Other (please specify)	☐	☐
o. None	☐	☐

Please specify reasons for insufficient contraception from the following	**Yes**	**No**
a. Missed dose of oral contraceptives	☐	☐
b. Other medication or intercurrent illness interacting with oral contraception	☐	☐
c. Identified mishap with barrier method	☐	☐
d. Unknown	☐	☐
e. Had the patient committed to complete and continuous abstinence	☐	☐
f. Was lenalidomide started despite the patient being pregnant?	☐	☐
g. Did the patient receive educational material on the potential risk of teratogenicity?	☐	☐
h. Was the patient instructed on the need to avoid pregnancy?	☐	☐

Background Information on Reason for Pregnancy

PRENATAL INFORMATION		
Last date of Menstrual Period**:**	Expected date of delivery:	
Pregnancy tests	**Reference range**	**Date**
Urine qualitative		
Serum quantitative		

PAST OBSTETRIC HISTORY						
Year of Pregnancy	**Outcome**					
	Spontaneous abortion	**Therapeutic abortion**	**Live birth**	**Still Birth**	**Gestational age**	**Type of delivery**

BIRTH DEFECTS	**Yes**	**No**	**Unknown**

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Were there any birth defects in any previous pregnancies?	☐	☐	☐
Is there any family history of any congenital abnormality?	☐	☐	☐
If the answer to any of these questions is yes, please provide more details below			

MOTHER'S MEDICAL HISTORY/MATERNAL PAST MEDICAL HISTORY				
Condition	**Date**		**Treatment**	**Result**
	From	**To**		

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MOTHER'S/Maternal CURRENT MEDICAL CONDITION		
Condition	**From**	**Treatment**

MOTHER'S/ MATERNAL SOCIAL HISTORY	Yes	No
Alcohol	☐	☐
If yes, quantity/units per day:		
Tobacco	☐	☐
If yes, quantity per day		
IV or recreational drug use	☐	☐
If yes, please specify		

USE OF MATERNAL MEDICINES DURING PREGNANCY AND 4 WEEKS BEFORE PREGNANCY (Including herbal, alternative and uncontrolled medicines and dietary supplements)			
Medication/treatment	**Start date**	**End Date / Continuation**	**Indication**

Name of the person completing this form	Signature	Date

Please be aware that information provided to Cipla relating to you, may be used to comply with applicable laws and regulations. By providing us with information, you are consenting to the control and processing of this personal or sensitive data by Cipla.

Cipla