Zelvina® (Lenalidomide) Pregnancy Reporting Form Lenalidomide

Approved by the Malta Medicines Authority on the 02nd of February 2024.

Pregnancy Reporting Form
Lenalidomide

Please complete this form to report a pregnancy in a patient (or in a female partner of a male patient) treated with lenalidomide. Please send them immediately. Contact details are given below.

Marketing Authorisation Holder:

Adalvo Limited
Malta Life Sciences Park,
Building 1, Level 4
Sir Temi Zammit
San Gwann Industrial Est, SGN 3000
San Gwann, Malta

Tel: +40727251514
Email: pharmacovigilance@adalvo.com

REPORTING OF ADVERSE REACTIONS

Suspected adverse reactions and medication errors should be reported either to:

ADR Reporting, The Medicines Authority, Post-Licensing Directorate,
Sir Temi Zammit Buildings, Malta Life Sciences Park,
San Gwann SGN 3000, Malta
Website: www.medicinesauthority.gov.mt
e-mail: postlicensing.medicinesauthority@gov.mt

OR

The Marketing Authorisation holder as per details presented above.

INTIAL PREGNANCY REPORT FORM			
REPORTER INFORMATION			
Reporter Name:		**Occupation:**	
Address:		**City, Country:**	
Phone No.:		**Email address:**	
Fax No.:			
FEMALE PATIENT INFORMATION			
Patient ID:	**Age:**	**Date of Birth:**	
FEMALE PARTNER OF MALE PATIENT			
ID:	**Age:**	**Date of Birth:**	
PATIENT TREATMENT INFORMATION: LENALIDOMIDE CAPSULE			
Batch No.	**Expiry Date:**	**Dose:**	**Frequency:**
Start Date:		**Stop Date:**	

Indication for Use:

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 PROGRAMME		
	Yes	**No**
Was patient erroneously considered not to be of childbearing potential?		
If yes, state reason for considering not to be of childbearing potential.		
a. Age ≥ 50 years and naturally amenorrhoeic for ≥ 1 year		
b. Premature ovarian failure confirmed by a specialist gynaecologist		
c. Previous bilateral salpingo-oophorectomy, or hysterectomy		
d. XY genotype, Turner syndrome, uterine agenesis.		
Indicate from the list below what contraception was used:	**Yes**	**No**
a. Implant		
b. Levonorgestrel-releasing intrauterine system (IUS)		
c. Medroxyprogesterone acetate depot		
d. Tubal sterilization (specify below)		
I. Tubal ligation		
II. Tubal diathermy		
III. Tubal clips		
e. Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses.		
f. Ovulation inhibitory progesterone-only pills (i.e., desogestrel)		
g. Other progesterone-only pills		
h. Combined oral contraceptive pill		
i. Other intra-uterine devices		
j. Condoms		
k. Cervical cap		
l. Sponge		
m. Withdrawal		
n. Other		
o. None		
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		
Had the patient committed to complete and continuous abstinence?		
Was lenalidomide started despite the patient already being pregnant?		
Did the patient receive educational materials on the potential risk of teratogenicity?		
Did the patient receive instructions on the need to avoid pregnancy?		

PRENATAL INFORMATION

Date of last menstrual period:	**Estimated Delivery Date:**

Pregnancy test	**reference range**	**Date**
Urine Qualitative		
Serum quantitative		

PAST OBSTRETRIC HISTORY

Year of pregnancy	**Outcome**					
	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 any 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:		

Tobacco		
If yes, amount per day:		
IV or recreational drug use		
If yes, provide details.		

MATERNAL MEDICATION DURING PREGNANCY AND IN 4 WEEKS BEFORE PREGNANCY

(including herbal, alternative and over the counter medicines and dietary supplements)

Medication/treatment	Start Date	Stop Date/ Continuing	Indication

NAME OF PERSON COMPLETING THIS FORM	SIGNATURE	DATE