Lenalidomide

Pregnancy Report Form

UK

Pregnancy reports must be sent to Glenmark Pharmaceuticals Europe Ltd. IMMEDIATELY

This form must be returned to:

Glenmark Pharmaceuticals Europe Ltd.
Phone: 0800 458 0383
Email: medical_information@glenmarkpharma.com

Date of Awareness:	D	D	M	O	N	Y	Y	Y	Y

NOTE: Please use the first three letters of the month (e.g.: JAN)

Patient Data:

Sex of Patient: ☐ Female ☐ Male

☐ Pregnancy of Patient ☐ Pregnancy of Patient's Partner **OR** ☐ Exposure of a Pregnant Female

Pregnant Woman's Initials:				Date of Birth:	D	D	M	O	N	Y	Y	Y	Y	Age:	

Patient Initials (Who received drug):				Date of Birth:	D	D	M	O	N	Y	Y	Y	Y	Age:	

First, Middle, Last Names

Drug Name:	

Date of First Dose:	D	D	M	O	N	Y	Y	Y	Y	Last Dose:	D	D	M	O	N	Y	Y	Y	Y

Pregnancy initially diagnosed by: ☐ Home Urine Test ☐ Office Urine Test ☐ Serum Test

Date of Pregnancy Test:	D	D	M	O	N	Y	Y	Y	Y

Last Menstrual Period:	D	D	M	O	N	Y	Y	Y	Y

Female is Currently: ☐ Weeks' pregnant **OR** ☐ No longer pregnant ☐ Unknown

Female has Elected to: ☐ Carry Pregnancy to Term ☐ Terminate Pregnancy

Expected Date of Delivery:	D	D	M	O	N	Y	Y	Y	Y

Date Performed or Pending:	D	D	M	O	N	Y	Y	Y	Y

Reporter's Information:

Name:	Date:	D	D	M	O	N	Y	Y	Y	Y

Contact Information/ Address ☐ GB ☐ Northern Ireland		
	Signature:	
	Telephone:	
	Email:	
	Fax:	

Patient's Prescribing Physician's Information:

Name:	Date:	D	D	M	O	N	Y	Y	Y	Y

Contact Information/ Address ☐ GB ☐ Northern Ireland		
	Signature:	
	Telephone:	
	Email:	
	Fax:	

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Background Information on Reason for Pregnancy:

Was patient erroneously considered not to be of childbearing potential? ☐ Yes ☐ No

If yes, state reason for considering not to be of childbearing potential

- Age ≥ 50 years and naturally amenorrhoeic* for ≥ 1 year ☐ Yes ☐ No
  *amenorrhoea following cancer therapy or during breastfeeding does not rule out childbearing potential
- Premature ovarian failure confirmed by a specialist gynaecologist ☐ Yes ☐ No
- Previous bilateral salpingo-oophorectomy, or hysterectomy ☐ Yes ☐ No
- XY genotype, Turner syndrome, uterine agenesis ☐ Yes ☐ No

Indicate from the list below what contraception was used

- Implant ☐ Yes ☐ No
- Levonorgestrel-releasing intrauterine system (IUS) ☐ Yes ☐ No
- Medroxyprogesterone acetate depot ☐ Yes ☐ No
- Tubal sterilisation (specify below) ☐ Yes ☐ No
  - Tubal ligation ☐ Yes ☐ No
  - Tubal diathermy ☐ Yes ☐ No
  - Tubal chips ☐ Yes ☐ No
- Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses ☐ Yes ☐ No
- Ovulation inhibitory progesterone-only pills (i.e. desogestrel) ☐ Yes ☐ No
- Other progesterone-only pills ☐ Yes ☐ No
- Combined oral contraceptive pill ☐ Yes ☐ No
- Other intra-uterine devices ☐ Yes ☐ No
- Condoms ☐ Yes ☐ No
- Cervical cap ☐ Yes ☐ No
- Sponge ☐ Yes ☐ No
- Withdrawal ☐ Yes ☐ No
- Other ☐ Yes ☐ No
- None ☐ Yes ☐ No

Indicate from the list below the reason for contraceptive failure

- Missed oral contraception ☐ Yes ☐ No
- Other medication or intercurrent illness interacting with oral contraception ☐ Yes ☐ No
- Identified mishap with barrier method ☐ Yes ☐ No
- Unknown ☐ Yes ☐ No
- Had the patient committed to complete and continuous abstinence ☐ Yes ☐ No
- Was the drug started despite patient already being pregnant ☐ Yes ☐ No
- Did patient receive educational materials on the potential risk of teratogenicity ☐ Yes ☐ No
- Did patient receive instructions on need to avoid pregnancy ☐ Yes ☐ No

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Background Information on Reason for Pregnancy

Prenatal information

Date of Last Menstrual Period:	D	D	M	O	N	Y	Y	Y	Y
Estimated Delivery Date:	D	D	M	O	N	Y	Y	Y	Y

Pregnancy test

Urine Qualitative		Reference Range:		Date:	D	D	M	O	N	Y	Y	Y	Y
Serum Quantitative		Reference Range:		Date:	D	D	M	O	N	Y	Y	Y	Y

Past Obstetric History

Year of Pregnancy	Outcome				Gestational Age	Type of Delivery
Y Y Y Y	☐ Spontaneous abortion	☐ Therapeutic abortion	☐ Live birth	☐ Still birth		
Y Y Y Y	☐ Spontaneous abortion	☐ Therapeutic abortion	☐ Live birth	☐ Still birth		
Y Y Y Y	☐ Spontaneous abortion	☐ Therapeutic abortion	☐ Live birth	☐ Still birth		

Birth defects

Was there any birth defect from any pregnancy?	☐ Yes	☐ No	☐ Unknown
Is there any family history of any congenital abnormality abstinence?	☐ Yes	☐ No	☐ Unknown

If yes to either of these questions, please provide details below:

Maternal Past Medical History

Condition	Dates		Treatment	Outcome
	From:	D D M O N Y Y Y Y		
	To:	D D M O N Y Y Y Y		
	From:	D D M O N Y Y Y Y		
	To:	D D M O N Y Y Y Y		
	From:	D D M O N Y Y Y Y		
	To:	D D M O N Y Y Y Y		

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Maternal Current Medical Conditions

Condition	From	Treatment
	D D M O N Y Y Y Y	
	D D M O N Y Y Y Y	
	D D M O N Y Y Y Y	
	D D M O N Y Y Y Y	
	D D M O N Y Y Y Y	

Maternal Social History

Alcohol ☐ Yes ☐ No	Tobacco ☐ Yes ☐ No	IV or recreational drug use ☐ Yes ☐ No
If yes, amount/units per day:	If yes, amount per day:	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	Dates	Indication
	Start: D D M O N Y Y Y Y	
	Stop/Continuing: D D M O N Y Y Y Y	
	Start: D D M O N Y Y Y Y	
	Stop/Continuing: D D M O N Y Y Y Y	
	Start: D D M O N Y Y Y Y	
	Stop/Continuing: D D M O N Y Y Y Y	
	Start: D D M O N Y Y Y Y	
	Stop/Continuing: D D M O N Y Y Y Y	

Name of person completing this form

Name:		Signature:
Date:	D D M O N Y Y Y Y	

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Under applicable law, you may have the right to access and verify your personal information held by Glenmark Pharmaceuticals Europe Ltd., receive a copy of it, obtain its correction and deletion if it is inaccurate and object to certain processing. If you wish to exercise those rights, you can contact our data protection officer at: dpo.glenmark@glenmarkpharma.com. You may also have the right to lodge a complaint with the supervisory authority enforcing data protection by visiting this URL: https://ico.org.uk/

Reporter's Signature (required):

Signature:

Date:	D	D	M	O	N	Y	Y	Y	Y

On behalf of Glenmark Pharmaceuticals Europe Ltd., thank you for providing information that will assist us in our commitment to patient safety.

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Date of preparation of text: January 2023
NP-UK--0033
Version 1.0
Approved by MHRA: November 2022

Lenalidomide

Event-Specific Questionnaire for HCP – Pregnancy Outcome Form

UK

This form must be returned to:

Glenmark Pharmaceuticals Europe Ltd.
Phone: 0800 458 0383
Email: medical_information@glenmarkpharma.com

NOTE: Please use the first three letters of the month (e.g.: JAN)

Reporter information

Reporter Name:

Address: City:

County, Country: ☐ GB ☐ Northern Ireland Telephone:

Email: Fax:

Patient information

Patient ID: Date of Birth: D D M O N Y Y Y Y

Ethnicity: ☐ White ☐ African-Caribbean Other, specify:

Partner of patient information

☐ Not applicable Ethnicity: ☐ White ☐ African-Caribbean Other, specify:

Pregnancy outcome

Date of delivery: D D M O N Y Y Y Y Gestation age at delivery:

Normal	☐ Yes	☐ No
C-section	☐ Yes	☐ No
Induced	☐ Yes	☐ No
Ectopic pregnancy	☐ Yes	☐ No
Elective termination	☐ Yes	☐ No
Spontaneous abortion (≤20 weeks)	☐ Yes	☐ No
Foetal death/stillbirth (>20 weeks)	☐ Yes	☐ No
Were the products of conception examined?	☐ Yes	☐ No

Date: D D M O N Y Y Y Y

Weeks from LMP:

If yes, was the foetus normal?

☐ Yes ☐ No ☐ Unknown

If no, describe below:

Obstetrics information

Complications during pregnancy	☐ Yes	☐ No	If yes, please specify
Complications during labour/delivery	☐ Yes	☐ No	If yes, please specify
Post-partum maternal complications	☐ Yes	☐ No	If yes, please specify

Foetal outcome

Neonatal complication	☐ Yes	☐ No	If yes, please specify
Birth defect noted	☐ Yes	☐ No	If yes, please specify
Live normal infant	☐ Yes	☐ No	
Foetal distress	☐ Yes	☐ No	
Intra-uterine growth retardation	☐ Yes	☐ No	

Sex: ☐ Male ☐ Female

Birth weight: _____ lbs _____ oz. or _____ kg

Length: _____ inches, or _____ cms

Apgar score: 1 min _____ 5 min _____ 10 min _____

☐ Unknown

Signature of person completing this form

Signature:

Date: D D M O N Y Y Y Y

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Reporter's Signature (required):

Signature:	Date:	D	D	M	O	N	Y	Y	Y	Y

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Date of preparation of text: January 2023
NP-UK--0039
Version 1.0
Approved by MHRA: November 2022

Lenalidomide

Adverse Event Form

UK

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Phone: 0800 458 0383
Email: medical_information@glenmarkpharma.com

NOTE: Please use the first three letters of the month (e.g.: JAN)

Case No:

☐ GB ☐ Northern Ireland

☐ New ☐ Follow-up

For Glenmark use only		For Studies Enter	
Date of Receipt:	D D M O N Y Y Y Y	Protocol:	
Received by: (Name and organisation e.g. CRO, or company representative)		Site Number:	
		Patient Number:	

Source: ☐ Spontaneous ☐ Comp. Use ☐ Lit. Other, specifiy: _____

Suspect Drug

Drug, Dosage-form, Strength, Route (e.g. Tab 5mg, oral)	Dose and Frequency	Lot/ Batch no.	Therapy start date:	Therapy stop date:	Drug-Event Causal relationship Other, Specify (Causal relationship 1 = Not related, 2 = Related)	Indication for use of drug

Action Taken

☐ None ☐ Dose decreased, specify ☐ Permanently discontinued ☐ Not applicable

☐ Unknown ☐ Dose increased, specify ☐ Temporarily interrupted

Patient Data

Initials: | Date of Birth: D D M O N Y Y Y Y | Age:

Weight: kg | Height: cm | Gender: ☐ Male ☐ Female

Adverse Event

Description of Adverse Event (provide diagnosis if available) – symptoms and treatment:

Event onset date: D D M O N Y Y Y Y

Event stop date: D D M O N Y Y Y Y

Outcome of Adverse Event

☐ Recovered ☐ Unknown ☐ Death

☐ Recovered with sequelae ☐ Not recovered

Did the event result in hospitalisation or prolonged hospitalisation? ☐ Yes ☐ No

Date of death: D D M O N Y Y Y Y

Cause(s) of death:

If autopsy is performed please forward report.
Please attach relevant clinical laboratory assessments to confirm the event

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Case No:

☐ GB ☐ Northern Ireland

Medical History

☐ Yes (if yes, please specify)

☐ None ☐ Unknown

Other Medication (Medication taken in the last 3 months prior to the event)

Drug, Dosage-form, Strength, Route (eg. Tab 5mg, oral)	Dose and Frequency	Therapy start date:	Therapy stop date:	Indication for use of drug

Has the patient discussed this event with their healthcare professional? ☐ Yes (If yes, would you please provide their healthcare professional's contact information below?) ☐ No ☐ Unknown

Healthcare professional's contact information

Name:

Address: City:

County, Country: ☐ GB ☐ Northern Ireland Telephone:

Email: Fax:

Reporter

☐ Physician ☐ Nurse ☐ Pharmacist ☐ Patient ☐ Relative ☐ Other, specify

Name:

Address: City:

County, Country: ☐ GB ☐ Northern Ireland Telephone:

Email: Fax:

Pharmacy Name (if applicable)

Name: Email:

Signature

Signature:

Date of AE awareness: D D M O N Y Y Y Y

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Case No:	

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This section applies only if the reporter is the patient or anyone but the prescriber/physician/HCP.

Please chose one, as applicable:

☐ I grant Glenmark Pharmaceuticals Europe Ltd. permission to contact the prescriber/physician/HCP who treated me/the affected patient when the side effect(s) occurred and authorise him/her to provide data from my medical record related to the event(s) occurred.

☐ No, I do not grant Glenmark Pharmaceuticals Europe Ltd. permission to contact the prescriber/physician/HCP who treated me/the patient.

If you grant Glenmark Pharmaceuticals Europe Ltd. permission, please provide the information of the prescriber/physician/HCP

Contact information

Name:			
Address:		City:	
County, Country:	☐ GB ☐ Northern Ireland	Telephone:	
Email:		Fax:	

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A new way for a new world

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Version 1.0
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