Lenalidomide
Adverse Event Form

UK

This form must be returned to Accord: Accord-UK Ltd, Whiddon Valley, Barnstaple, Devon, EX32 8NS, United Kingdom
Phone: 01271 385257 Fax: 01271 346106 Email: rmpteam@accord-healthcare.com

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

◯ New ◯ Follow-up

Case No:

For Accord use only

Date of receipt: DD MM YYYY

Received by: (Name and organization – eg CRO, or company representative)

Source: ◯ Spontaneous ◯ Comp. Use ◯ Lit. ◯ Other, specify

For Studies Enter

Protocol/:

Site Number:

Patient Number:

Suspect Drug

Drug, Dosage-form, Strength, Route (Drug, Dosage-form, Strength, Route) (eg. Tab 5mg, oral)	Dose & frequency	Lot/ Batch no.	Therapy start date: DD/ MM / YYYY	Therapy stop date: DD/ MM / YYYY	Drug-Event Causal relationship Other, Specify (Causal relationship 1 = Not related, 2 = Related)	Indication for use of drug
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Action Taken

◯ None ◯ Unknown ◯ Not Applicable
◯ Dose decreased, specify ◯ Permanently discontinued
◯ Dose increased, specify ◯ Temporarily interrupted

Patient Data

Initials: | Date of Birth: DD MM YYYY | Age:

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

Adverse Event

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

Event onset date: DD MM YYYY

Event stop date: DD MM YYYY

Outcome of Adverse Event

◯ Recovered
◯ Recovered with sequelae
◯ Not recovered
◯ Unknown
◯ Death

Date of death: DD MM YYYY

Cause(s) of death:

Did the event result in hospitalization or prolonged hospitalization? ◯ Yes ◯ No

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

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Medical History

◯ Yes (if yes, please specify)
◯ None
◯ Unknown

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

Drug, Dosage-form, Strength, Route (Drug, Dosage-form, Strength, Route) (eg. Tab 5mg, oral)	Dose & frequency	Therapy Start date: DD / MM / YYYY	Therapy Stop date: DD / MM / YYYY	Indication for use of drug
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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:		Country:	
Address:		Fax:	
		Phone:	
		Email:	

Reporter

◯ Physician ◯ Nurse ◯ Pharmacist ◯ Patient ◯ Relative ◯ Other, please specify

Name:		Country:	
Address:		Fax:	
		Phone:	
		Email:	

Pharmacy Name (if applicable)

Name:		Email:	

Signature

Sign:		Date of AE awareness:	DD	MM	YYYY

accord

MHRA approval date 20/05/2021
BBBB2830

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Case No:	

Drug Safety Data Privacy notice

Your personal data will be processed by Accord-UK Ltd, Whiddon Valley, Barnstaple, EX32 8NS, United Kingdom. For further information on how Accord-UK Ltd processes your personal data along with your rights, please refer to our privacy notice located at https://www.accord-healthcare.com/

This section applies only if the reporter is the patient or anyone but the prescriber/physician/HCP. Please chose one, as applicable:

- ◯ I grant Accord 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 Accord permission to contact the prescriber/physician/HCP who treated me/the patient.

If you grant Accord permission, please provide the information of the prescriber/physician/HCP

Contact information

Name:		Country:	
Address:		Fax:	
		Phone:	
		Email:	