Revlimid® ▼ (lenalidomide)
Adverse Event Form

UK

This form must be returned to Bristol-Myers Squibb (BMS) Medical Information:
Phone: 0800 731 1736, Email: medical.information@bms.com.

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

Case No:

○ New ○ Follow-up

○ GB ○ Northern Ireland

For BMS use only

Date of receipt: DD MON YYYY

Received by: (Name and organisation – 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 (eg. Tab 5mg, oral)	Dose & frequency	Lot/ Batch no.	Therapy start date: DD/MON /YYYY	Therapy stop date: DD/MON /YYYY	Drug-Event Causal relationship Other, Specify (Causal relationship 1 = Not related, 2 = Related)	Indication for use of drug
			/ /	/ /		
			/ /	/ /		
			/ /	/ /		
			/ /	/ /		
			/ /	/ /		

Action Taken

○ None ○ Unknown ○ Not applicable

○ Dose decreased, specify ○ Permanently discontinued

○ Dose increased, specify ○ Temporarily interrupted

Patient Data

Initials: | Date of Birth: DD MON 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 MON YYYY

Event stop date: DD MON YYYY

Outcome of Adverse Event

○ Recovered
○ Recovered with sequelae
○ Not recovered
○ Unknown
○ Death

Date of death: DD MON YYYY

Cause(s) of death:

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

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

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Case No:

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 & frequency	Therapy start date: *DD/MON /YYYY*	Therapy stop date: *DD/MON /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:
Address:
Country:
Fax:
Phone:
Email:
◯ GB ◯ Northern Ireland

Reporter

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

Name:
Address:
Country:
Fax:
Phone:
Email:
◯ GB ◯ Northern Ireland

Pharmacy Name (if applicable)

Name:
Email:

Signature

Sign:
Date of AE awareness: *DD* *MON* *YYYY*

UK

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Case No:	

Data Privacy notice

Your personal data will be processed by Bristol-Myers Squibb Pharma EEIG (hereinafter "BMS"), as marketing authorisation holder of pharmaceutical products and its worldwide Affiliates, to the extent and for as long as necessary, for the purposes of the compliance with drug safety legal obligations and for storage purposes.

To conduct risk management programme activities, we may use third party service providers, who will handle directly any reporting relating to pregnancy, acting on our behalf, and upon our prior instructions.

BMS may disclose your personal information to regulatory authorities, affiliates of the BMS Group, service providers or other collaborators. Some of these entities may be located outside of the UK. BMS will take appropriate measures, such as implementing standard data protection clauses, to ensure that your personal information will be kept secure in accordance with applicable data protection law. BMS will only retain your personal data for the length of time required by law.

Under applicable law, you may have the right to access and verify your personal information held by BMS, 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: eudpo@bms.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/

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

- ◯ I grant BMS 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) that have occurred.
- ◯ No, I do not grant BMS permission to contact the prescriber/physician/HCP who treated me/the patient.

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

Contact information

Name:		Fax:	
Address:		Phone:	
		Email:	
Country:		◯ GB ◯ Northern Ireland	

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.

Bristol Myers Squibb™