Thalidomide
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

☐ New ☐ Follow-up

Case No:

For Accord use only

Date of receipt: DD MON YYYY

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

Source: ☐ Spontaneous ☐ Solicited ☐ 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/ 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 hospitalization or prolonged hospitalization? ☐ Yes ☐ No

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

accord

MHRA approval date 25/09/2020
BBBB2817

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

Case No:	

Medical History

Current or past relevant medical history (including concurrent illness, allergy, smoking, alcohol abuse)

☐ 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 / MON / YYYY	Therapy Stop date: DD / MON / YYYY	Indication for use of drug
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

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	MON	YYYY

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

Case No:	

This section applies only if the reporter is the patient or anyone but not a healthcare professional 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

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

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/