Lenalidomide Krka (lenalidomide)

Adverse Event (AE) Form

This form must be returned to KRKA, d.d., Novo mesto; Telephone✆: +353 1 413 3710; Email✉: pharmacovigilance.IE@krka.biz

For Krka use only				**Case no:**
Date of receipt: DD MM YYYY				
Received by:				
Report type:		☐ New		☐ Follow up
Source:	☐ literature	☐ Health professional	☐ Patient	☐ Other (sepecify)
For studies enter:		Protocol no:	Site no:	Patient no:

Patient Data					
Initials:	Date of birth: DD MM YYYY	Age:	Weight (kg):	Heigth(cm):	Sex:

Suspected Drug

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

Action taken

☐ None	☐ Unknown	☐ Not applicable	☐ Dose decreased, specify	☐ Dose increased, specify	☐ Permanently discontinued	☐ Temporarily interrupted

Adverse Event	Event on-set date: DD/MM/YYYY	Event stop date: DD/MM/YYYY	Or ongoing at time of reporting (If less than 24 hours):HOUR/MIN

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

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 hospitalisation or prolonged hospitalisation? YES/NO:		**If autopsy is performed please forward report. Please attach relevant clinical laboratory assessments to confirm the event**	

Medical History

☐ 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:**	**Therapy end date:**	**Indication for use of drug**
		DD/MM/YYYY	DD/MM/YYYY	
		DD/MM/YYYY	DD/MM/YYYY	
		DD/MM/YYYY	DD/MM/YYYY	
		DD/MM/YYYY	DD/MM/YYYY	
		DD/MM/YYYY	DD/MM/YYYY	
Has the patient discussed this event with their healthcare professional?	☐ No			
	☐ If yes, would you please provide their healthcare professional's contact information below?			

	☐ Unknown

Healthcare professional's contact information	
Name:	Phone:
Address:	Email:
	Fax:

Pharmacy Name (if applicable):	
Name:	**Email:**

Reporter details	
Profession:	Phone:
Name:	Email:
Address:	Fax:
Signature:	Date of AE awareness: DD/MM//YYYY

Data Privacy Notice

We would like to notify you that you will share your personal data (aggregated anonymised patient limited data e.g., patient intials, date of birth) with KRKA SUBSIDIARY when you'll report adverse reaction or ask a question about the safety of our medicine. Because of the new EU data protection legislation we have to inform you that:

- We will process your data only for these purposes.

- That we have an obligation to process them and to store them permanently according to legislation governing medicinal products.

- Personal data protection policy and the rights of individuals are available on our website (www.krka/biz).