Lenalidomide Adverse Event Form

Australia

This form must be returned to Cipla. Email: Lenalidomide.cipla@cipla.com

Phone: 1800 87 86 85

☐ New ☐ Follow-up

For Cipla Use
Date of receipt:
Received by: (Name and organization – e.g. CRO, or company representative)
Source: ☐ Spontaneous ☐ Comp. Use ☐ Other, specify

Reporter Details		
1. Name and Address of Reporter _____ _____ _____	☐ Health Authority ☐ Health Professional: ☐ MD ☐ Pharmacist ☐ Other ☐ Patient ☐ Literature citation ☐ Relative ☐ Other, specify	**Email:** **Phone:** **Country:** **Occupation:**
Sign & Date _____		

Patient Details						
2. Reference#	3. Patient Initials	4. Sex ☐ M ☐ F	5. Date ADR Reported (dd/mmm/yy)	6. Initial Report ☐ Follow-up Report ☐		7. Weight
8. Country	9. Date of Birth (dd/mmm/yy)	10. Age	11. Date of ADR Onset (dd/mmm/yy)	12. Pregnant at Time of Event(s)? ☐ Yes	☐ No ☐ NA	13. Height
14. Medical history ☐ Yes (if yes, please specify) ☐ None ☐ Unknown						
15. Family history						
16. Concomitant Conditions:						

Approved by TGA: November 2022

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Suspected Medicinal Product(s)							
17. Suspect Medication (Brand Name & INN)	18. Dose, Dosage-form, Strength & Frequency	19. Route of Administration	20. Lot # & Exp. Date	21. Relationship of the event to the suspected medication (Related/ Not Related (Causal relationship 1 = Not related, 2 = Related)	22. Indication	23. Treatment start and stop Dates (dd/mmm/yy)	24. Duration of Treatment

25. Action taken with respect to Suspect Drug?

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

Concomitant medicinal products						
26. Concomitant Medications (excluding those used to treat ADR)	27. Co-suspect ADR Drug? (Y / N)	28. Dose & Frequency	29. Route of Administration	30. Date of Administration		31. Indication
				From	To	

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Adverse Event		
32. Description of Adverse Event (provide a diagnosis if available) - symptoms and treatment:		
33. Relevant tests/laboratory data, including dates		
34. Check all that are appropriate to the event ☐ Patient died. Date of death (dd/mmm/yy):_____ ☐ Death attributed to the event(s) ☐ Emergency Room stay only ☐Hospitali-sation ☐ initial or ☐ prolonged From (dd/mmm/yy): To: ☐ Involved significant disability or incapacity ☐ Life-threatening ☐ Required intervention to prevent permanent damage ☐ Congenital anomaly ☐ Other. Specify other: _____ ☐ None of the Above: _____ ☐ Involved significant disability or incapacity **Has the patient discussed this event with their healthcare professional?** ⚐ Yes ☐ No ☐ Unknown	35. Outcome ☐ Recovered. Date: _____ ☐ Recovered with sequelae ☐ Not recovered ☐ Unknown • Death Date of death: Cause(s) of death: If an autopsy was performed, please forward the report. Please attach relevant clinical laboratory assessments to confirm the event	36. Event onset date: Event stop date:

37. Dechallenge/Rechallenge	YES	NO	N/A
Lenalidomide discontinued?	⚐	☐	☐
Reaction abated after stopping the drug?	⚐	☐	☐
Lenalidomide restarted?	⚐	☐	☐
Reaction reappeared after rechallenge?	⚐	☐	☐

Healthcare professional's contact information	
Name and Professional Address: Postcode: Date:	Tel No: Email: Speciality:

Pharmacy Name (if applicable)	
Name:	E mail:

Signature	
Sign:	Date of AE awareness:

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Data Privacy notice
Please be aware that information provided to Cipla relating to you may be used to comply with applicable laws and regulations. By providing us with information you are consenting to the control and processing of this personal or sensitive data by Cipla. Your personal data will be processed by Cipla. This section applies only if the reporter is the patient or anyone but the prescriber/physician/HCP. Please chose one, as applicable: ☐ I grant Cipla permission to contact the prescriber/physician/HCP who treated me/the affected patient when the side effect(s) occurred and a4uthorise him/her to provide data from my medical record related to the event(s) occurred. ☐ No, I do not grant Cipla permission to contact the prescriber/physician/HCP who treated me/the patient. If you grant Cipla permission, please provide the information of the prescriber/physician/HCP