CIPLA MEDPRO (PTY) LTD
Building 9, Parc du Cap Office Park
Mispel Street
Bellville
7530
Tel : (021) 943 4200
Fax : (021) 914 4699
Email : drugsafetysa@cipla.com

ADVERSE EVENT REPORT FORM

For Cipla SA DSU Use Only	
Initial Receipt Date:	
PV. Reference no:	
Argus Case no:	

Reporter Details

Source:	☐ Physician ☐ Nurse ☐ Pharmacist ☐ Consumer			
Name:				
Address:				
		Country:		
Email:		Tel:		

Patient Details

Initials:			Surname:			Date of Birth:	
Age:	yrs.		Weight (kg):			Height (cm):	
Gender:	☐ Male ☐ Female						

Adverse Event

Overall diagnosis of the event:	
Description of Adverse Event:	

Event onset date:		Event stop date:	
Treatment received:	☐ No ☐ Yes If Yes, please specify:		

Duration (If < 24 hours) ☐ Hours _____. ☐ Minutes_____. ☐ or ongoing at time of report

Outcome of adverse event:

☐ Recovered ☐ Recovered with sequelae ☐ Not recovered ☐ Unknown

Dechallenge: ☐ Yes ☐ No ☐ Not Applicable

Rechallenge: ☐ Yes ☐ No ☐ Not Applicable

Seriousness of the Event

(tick all that apply) ☐ Life-threatening ☐ Hospitalisation or prolonged hospitalisation ☐ Congenital anomaly/birth defect

☐ Persistent or significant disability or incapacity ☐ Other medically important condition or event ☐ Death

Date of death: DD/MM/YYYY

Possible cause of death:

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

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Medical History

(May be supplied as a copy of Medical file if up to date)

Current or past relevant medical history (incl. concurrent illness, allergy, smoking, alcohol abuse

☐ Yes ☐ No

If yes please specify:

Laboratory Tests & Findings relevant to the adverse event

(May be supplied as a copy of Medical file if up to date)

Suspect drug

	Drug Name, Strength	Dose & frequency	Route	Therapy start date: (DD/MM/YYYY)	Therapy stop date: (DD/MM/YYYY)	Batch details	Indication for Use

Action taken with suspect drug:

☐ Continued unchanged ☐ Continued, dose or dose regimen changed, specify: _____.

☐ Withdrawn ☐ Not applicable

Causal relationship: ☐ Not related ☐ Related ☐ Unknown

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Other Medication

Medication taken during the past 3 months prior to the event **May be supplied as a copy of Medical file if up to date**

	Drug Name, Strength	Dose & frequency	Route	Therapy start date: (DD/MM/YYYY)	Therapy stop date: (DD/MM/YYYY)	Indication for Use

For Cipla SA DSU Use Only

☐ Initial Report ☐ Follow-up report

	Name:	
	Title:	
	Date of Follow-up:	
	Additional information:	