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

EXPOSURE DURING PREGNANCY 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:	South Africa	
Email:		Tel:		

Patient Details

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

Relevant drug(s) exposure before/during pregnancy

Drug Name	**Dose & frequency**	**Route**	**Therapy start date:** (DD/MM/YYYY)	**Therapy stop date:** (DD/MM/YYYY)	**Batch number**	**Indication for Use**
Drug taken by	☐ Father ☐ Mother					

Action taken with suspect drug:

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

☐ Withdrawn ☐ Not applicable

Adverse Event

Did the patient experience an 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

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Outcome of adverse event:

☐ Recovered ☐ Recovered with sequelae ☐ Not recovered ☐ Unknown

Dechallenge: ☐ Yes ☐ No ☐ Not Applicable

Rechallenge: ☐ Yes ☐ No ☐ Not Applicable

Pregnancy Information

Date of 1st day of last menstrual period:			Estimated date of delivery:	
Gestation at time of initial exposure:			Date pregnancy confirmed:	
Pregnancy test:	☐ Positive urine test	☐ Positive blood test	☐ Positive ultrasound	

Pregnancy Outcome

Outcome of birth:	☐ Full term live birth	☐ Still birth	☐ Induced abortion	☐ Spontaneous abortion/miscarriage
	☐ Congenital anomaly/birth defect	☐ Not known at this date		
Date of delivery:		Gestational age at birth(weeks):		
Mode of delivery:				
Additional comments on pregnancy/delivery:				

Infant(s) information

Infant number	Gender of infant	Infant length(cm)	Infant weight (kg)	APGAR score	Exposure during breastfeeding
1	☐ M ☐ F				☐ Yes ☐ No
2	☐ M ☐ F				☐ Yes ☐ No
3	☐ M ☐ F				☐ Yes ☐ No

Medical History

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

Current or past relevant medical history (with focus on relevant prior gynaecological/obstetric history)

☐ Yes ☐ No

If yes, please specify:

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☐ Initial Report ☐ Follow-up report

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