

Pregnancy Reporting Form (Antepartum Information)

Please complete this form to report a pregnancy in:

- a female patient treated with pomalidomide or
- a female partner of a male patient treated with pomalidomide.

Please email immediately to Aurobindo (AB) at PharmacovigilanceBNL@aurobindo.com. As part of AB's Safety Monitoring System, we may require further information on reported pregnancies. AB may therefore be in contact with you for further information in due course and would value your cooperation to ensure we are able to obtain all relevant information.

PATIENT IDENTIFIER: (FOR STUDIES, MUST INCLUDE PROTOCOL, SITE & SUBJECT NUMBERS)		CASE # (AB ONLY)		LOCAL COUNTRY NUMBER: (AB ONLY)	
<input type="text"/>		<input type="text"/>		<input type="text"/>	
AB RECEIPT DATE (AB USE ONLY)		Global RECEIPT DATE (AB USE ONLY)			
<input type="text"/>		<input type="text"/>			
REPORT TYPE:	<input type="checkbox"/> SPONTANEOUS OR		<input type="checkbox"/> STUDY		COUNTRY*
	<input type="checkbox"/> INITIAL REPORT OR		<input type="checkbox"/> FOLLOW-UP REPORT		*If UK, was Country of Incidence, Specify if Northern Ireland below? Yes <input type="checkbox"/> No <input type="checkbox"/>
EVENT: PREGNANCY					
EXPOSURE TYPE: <input type="checkbox"/> MATERNAL DRUG EXPOSURE OR <input type="checkbox"/> PATERNAL DRUG EXPOSURE					
FOR <u>PATERNAL DRUG EXPOSURE ONLY</u> : WAS PREGNANT PARTNER INFORMED CONSENT FORM SIGNED? <input type="checkbox"/> No <input type="checkbox"/> YES					
IF NO, DID THE MALE SUBJECT PROVIDE ALL OF THE PREGNANCY SURVEILLANCE INFORMATION BELOW? <input type="checkbox"/> No <input type="checkbox"/> YES					
REPORT TYPE: <input type="checkbox"/> PROSPECTIVE REPORT OR <input type="checkbox"/> RETROSPECTIVE REPORT					
WERE THERE ANY ADDITIONAL MATERNAL/PATERNAL ADVERSE EVENTS? <input type="checkbox"/> No <input type="checkbox"/> YES					
IF YES, REPORT THE ADVERSE EVENTS APPROPRIATELY (FOR STUDIES, REFER TO STUDY-SPECIFIC INSTRUCTIONS)					

MATERNAL INFORMATION DATE OF BIRTH: <input type="text"/>	AGE AT CONCEPTION: <input type="text"/>	HEIGHT: <input type="text"/> <input type="checkbox"/> inches <input type="checkbox"/> cm	WEIGHT: <input type="text"/> <input type="checkbox"/> lb <input type="checkbox"/> kg	RACE: <input type="checkbox"/> WHITE <input type="checkbox"/> BLACK <input type="checkbox"/> ASIAN <input type="checkbox"/> AMERICAN INDIAN OR ALASKAN NATIVE <input type="checkbox"/> NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER <input type="checkbox"/> Aboriginal <input type="checkbox"/> Torres Strait Islander <input type="checkbox"/> OTHER RACE: <input type="text"/>
	<input type="text"/>			

NUMBER OF PREGNANCIES INCLUDING THIS ONE		<input type="text"/>	NUMBER OF BIRTHS		<input type="text"/>	NUMBER OF LIVING CHILDREN		<input type="text"/>
ONSET DATE LAST MENSTRUAL PERIOD (LMP):	APPROXIMATE DATE OF CONCEPTION:			DATE PREGNANCY WAS CONFIRMED:				
	ESTIMATED DATE OF DELIVERY:			TEST METHOD: <input type="checkbox"/> SERUM <input type="checkbox"/> URINE				
ESTIMATED GESTATIONAL AGE WHEN PREGNANCY DIAGNOSED:			<input type="text"/>	WEEKS		DETERMINED BY:		<input type="checkbox"/> FETAL ULTRASOUND <input type="checkbox"/> DATE FROM LMP
CONTRACEPTION AT TIME OF CONCEPTION:			<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> UNKNOWN	(IF YES, SPECIFY) <input type="text"/>		

RELEVANT MATERNAL MEDICAL HISTORY/RISK FACTORS	DATE OF ONSET	IF APPLICABLE SPECIFY PERTINENT DETAILS
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>

PATERNAL INFORMATION:	AGE	<input type="text"/>	YEARS	DATE OF BIRTH:	<input type="text"/>
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RELEVANT PATERNAL MEDICAL HISTORY/RISK FACTORS	DATE OF ONSET	IF APPLICABLE SPECIFY PERTINENT DETAILS
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>

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PATIENT IDENTIFIER: <small>(FOR STUDIES, MUST INCLUDE PROTOCOL, SITE & SUBJECT NUMBERS)</small>	CASE # (AB ONLY)	LOCAL COUNTRY NUMBER: (AB ONLY)					
MEDICATION NAME AND INDICATION	PREGNANCY RELATED TO MEDICATION?*	DOSE AND UNITS	FREQ	ROUTE **	PERIOD(S) OF DRUG EXPOSURE ***	ONCOLOGY DRUGS ONLY	START AND STOP DATES
1. <input style="width: 100%;" type="text"/> INDICATION <input style="width: 100%;" type="text"/> <input type="checkbox"/> MATERNAL OR <input type="checkbox"/> PATERNAL <input type="checkbox"/> NON-STUDY OR <input type="checkbox"/> STUDY	<input type="checkbox"/> NOT RELATED <input type="checkbox"/> RELATED	<input style="width: 100%; height: 40px;" type="text"/>	<input style="width: 100%; height: 40px;" type="text"/>	<input style="width: 100%; height: 40px;" type="text"/>	<input style="width: 100%; height: 40px;" type="text"/>	CYCLE #: <input style="width: 100%;" type="text"/> CUMULATIVE DOSE WITH UNITS <input style="width: 100%;" type="text"/>	<input type="checkbox"/> ONGOING
2. <input style="width: 100%;" type="text"/> INDICATION <input style="width: 100%;" type="text"/> <input type="checkbox"/> MATERNAL OR <input type="checkbox"/> PATERNAL <input type="checkbox"/> NON-STUDY OR <input type="checkbox"/> STUDY	<input type="checkbox"/> NOT RELATED <input type="checkbox"/> RELATED	<input style="width: 100%; height: 40px;" type="text"/>	<input style="width: 100%; height: 40px;" type="text"/>	<input style="width: 100%; height: 40px;" type="text"/>	<input style="width: 100%; height: 40px;" type="text"/>	CYCLE #: <input style="width: 100%;" type="text"/> CUMULATIVE DOSE WITH UNITS <input style="width: 100%;" type="text"/>	<input type="checkbox"/> ONGOING
3. <input style="width: 100%;" type="text"/> INDICATION <input style="width: 100%;" type="text"/> <input type="checkbox"/> MATERNAL OR <input type="checkbox"/> PATERNAL <input type="checkbox"/> NON-STUDY OR <input type="checkbox"/> STUDY	<input type="checkbox"/> NOT RELATED <input type="checkbox"/> RELATED	<input style="width: 100%; height: 40px;" type="text"/>	<input style="width: 100%; height: 40px;" type="text"/>	<input style="width: 100%; height: 40px;" type="text"/>	<input style="width: 100%; height: 40px;" type="text"/>	CYCLE #: <input style="width: 100%;" type="text"/> CUMULATIVE DOSE WITH UNITS <input style="width: 100%;" type="text"/>	<input type="checkbox"/> ONGOING
4. <input style="width: 100%;" type="text"/> INDICATION <input style="width: 100%;" type="text"/> <input type="checkbox"/> MATERNAL OR <input type="checkbox"/> PATERNAL <input type="checkbox"/> NON-STUDY OR <input type="checkbox"/> STUDY	<input type="checkbox"/> NOT RELATED <input type="checkbox"/> RELATED	<input style="width: 100%; height: 40px;" type="text"/>	<input style="width: 100%; height: 40px;" type="text"/>	<input style="width: 100%; height: 40px;" type="text"/>	<input style="width: 100%; height: 40px;" type="text"/>	CYCLE #: <input style="width: 100%;" type="text"/> CUMULATIVE DOSE WITH UNITS <input style="width: 100%;" type="text"/>	<input type="checkbox"/> ONGOING
5. <input style="width: 100%;" type="text"/>						CYCLE #: <input style="width: 100%;" type="text"/>	

INDICATION

MATERNAL OR PATERNAL NOT RELATED

NON-STUDY OR STUDY RELATED

CUMULATIVE

DOSE WITH UNITS

OR ONGOING

6.

INDICATION

MATERNAL OR PATERNAL NOT RELATED

NON-STUDY OR STUDY RELATED

CYCLE #:

CUMULATIVE

DOSE WITH UNITS

OR ONGOING

7.

INDICATION

MATERNAL OR PATERNAL NOT RELATED

NON-STUDY OR STUDY RELATED

CYCLE #:

CUMULATIVE

DOSE WITH UNITS

OR ONGOING

* MANDATORY FOR ALL STUDIES

**ROUTE:

- 1 = ORAL 2 = INTRAVENOUS 3 = SUBCUTANEOUS 4 = OTHER

***PERIOD(S) OF DRUG EXPOSURE: (INCLUDE ALL THAT APPLY)

- 0 = PRIOR TO CONCEPTION 1 = 1ST TRIMESTER 2 = 2ND TRIMESTER
- 3 = 3RD TRIMESTER 4 = LABOR & DELIVERY 5 = UNKNOWN

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PRENATAL DIAGNOSTIC TESTING	BASE-LINE	DATE	TEST RESULTS UNITS	NORMAL RANGE	
				LOW	HIGH
	<input type="checkbox"/>				
	<input type="checkbox"/>				
	<input type="checkbox"/>				
	<input type="checkbox"/>				
	<input type="checkbox"/>				
	<input type="checkbox"/>				
	<input type="checkbox"/>				

DESCRIBE RESULTS IN DETAIL, IF APPLICABLE:

REPORTER INFORMATION:

 AB STUDY INVESTIGATOR

 NON-AB STUDY SPONSOR

 OTHER*

***QUALIFICATION: (COMPLETE ONLY IF "OTHER" IS CHECKED)**

PHYSICIAN
 PHARMACIST
 NURSE/NURSE PRACTITIONER
 OTHER HEALTH PROFESSIONAL

CONSUMER
 ATTORNEY
 OTHER NON-HEALTH PROFESSIONAL

PERSON COMPLETING THE FORM (IF DIFFERENT FROM INVESTIGATOR/SPONSOR) :	DATE:
<input style="width: 90%;" type="text"/> PRINTED NAME	
<input style="width: 90%;" type="text"/> SIGNATURE	

INSTITUTION / ORGANIZATION:

STREET ADDRESS: <input style="width: 95%;" type="text"/>	CITY: <input style="width: 95%;" type="text"/>
	STATE / PROVINCE: <input style="width: 95%;" type="text"/>

POST CODE:	<input type="text"/>	COUNTRY:	<input type="text"/>	PHONE NUMBER:	<input type="text"/>
Email address	<input type="text"/>				
INVESTIGATOR/SPONSOR/OTHER:					
<input type="text"/>	LAST NAME				
<input type="text"/>	FIRST NAME	<input type="text"/>	MIDDLE INITIAL		
SIGNATURE:	<input type="text"/>			DATE:	<input type="text"/>