

# Lenalidomide Teva®

## Lenalidomide - Teratogenicity - Questionnaire

### INITIAL AND FU POST MARKETING PREGNANCY REPORT

(For mother, child and father exposure reports)

**Table 1: GENERAL DETAILS (for Teva internal use only)**

<b>Source</b> (multiple selection is allowed): <input type="checkbox"/> Spontaneous; <input type="checkbox"/> Solicited; <input type="checkbox"/> Literature; <input type="checkbox"/> Health Authority; <input type="checkbox"/> Patient/Consumer; <input type="checkbox"/> Other (specify) _____				
Report version: <input type="checkbox"/> Initial <input type="checkbox"/> Follow-up FU number: _____	Safety Database ID# (LRN/ Arisg number): _____	Local reference number (for internal use only): _____	Receiver's Name: _____	Date Received by Teva group (DD-MMM-YYYY): _____

**Table 2: REPORTER DETAILS**

<b>Reporter Type:</b> <input type="checkbox"/> Consumer / non-Health care professional; <input type="checkbox"/> Pharmacist; <input type="checkbox"/> Physician; <input type="checkbox"/> Other Health care professional; Occupation: _____			
Reporter Name: _____	Tel. No: _____	Address (includes country): _____	Does the company have the patient's permission to contact the reporter in the future for follow-up information? <input type="checkbox"/> YES <input type="checkbox"/> NO

**Table 3: PATIENT DETAILS**

Who does this report concern? <input type="checkbox"/> MOTHER / <input type="checkbox"/> CHILD*; Did Father take the Suspect product? <input type="checkbox"/> YES* <input type="checkbox"/> NO *Please complete section 5: PARENT DETAILS					
Patient Initials: _____	Date of Birth (DD-MMM-YYYY): _____	Age: _____	Gender: _____	Weight: _____	Height: _____

**Table 4: RELEVANT PATIENT MEDICAL HISTORY / LABS**

Chronic diseases (i.e. diabetes, hypertension, asthma, etc.)	
Other diseases/ labs:	
Tobacco smoking:	<input type="checkbox"/> YES <input type="checkbox"/> NO ; number of cigarettes per day: _____
Alcohol drinking:	<input type="checkbox"/> YES <input type="checkbox"/> NO

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**Table 5: PARENT DETAILS**

Parent	Initials	Date of Birth (DD-MMM-YYYY)	Age	Weight	Height
<b>Mother</b> (please fill this section for child report only)					
<b>Father</b> (please fill this section for father exposure report only)					

**Table 6: PREGNANCY INFORMATION**

Is the patient still pregnant? <input type="checkbox"/> Yes <input type="checkbox"/> No	Last menstrual period date (DD-MMM-YYYY): _____	Pregnancy Outcome (multiple selection is allowed):		
		<input type="checkbox"/> Normal (No foetal anomaly) <input type="checkbox"/> Live birth with fetal AEs <input type="checkbox"/> Congenital Malformation	<input type="checkbox"/> Spontaneous abortion <input type="checkbox"/> Induced abortion <input type="checkbox"/> Elective Abortion	<input type="checkbox"/> Ectopic pregnancy <input type="checkbox"/> Foetal death (stillbirth) <input type="checkbox"/> Other: _____
Number of fetuses: _____	Expected delivery date (DD-MMM-YYYY): _____	Delivery Date (DD-MMM-YYYY): _____	Child birth weight (kg): _____	Is the patient breast-feeding? <input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, Start Date: _____; Stop Date: _____

In case of **abnormal** current pregnancy outcome, please complete **Table 7**.

**Table 7: PREGNANCIES HISTORY INFORMATION (for past pregnancies)**

Past pregnancies outcomes (number of pregnancies):	
<input type="checkbox"/> Normal (_____);	
<input type="checkbox"/> Abortion(_____); Specify:_____	
<input type="checkbox"/> Birth defect/ Congenital abnormality; Specify:_____	
<input type="checkbox"/> Foetal death (stillbirth); Specify:_____	
<input type="checkbox"/> Other(_____); Specify:_____	
<input type="checkbox"/> Is there Family history of birth defects / congenital abnormalities? <input type="checkbox"/> YES <input type="checkbox"/> NO	
Specify:_____	

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**Table 8: ADVERSE EVENT/ SPECIAL SITUATION DETAILS DURING /AFTER PREGNANCY**

Adverse Event (s):	Onset Date (DD-MMM-YYYY):	End Date (DD-MMM-YYYY):	Outcome*: (please use the legend below)	Serious?	Seriousness criteria**: (please use the legend below)	Reporter Causality***: (please specify which suspect drug the causality concerns) (please use the legend below)
				<input type="checkbox"/> YES <input type="checkbox"/> NO		Suspect Drug 1 _____ Suspect Drug 2 _____ Suspect Drug 3 _____
				<input type="checkbox"/> YES <input type="checkbox"/> NO		Suspect Drug 1 _____ Suspect Drug 2 _____ Suspect Drug 3 _____
				<input type="checkbox"/> YES <input type="checkbox"/> NO		Suspect Drug 1 _____ Suspect Drug 2 _____ Suspect Drug 3 _____

**\*Outcome:** Recovered/ resolved =1; Recovering/Resolving =2; Not recovered/ not resolved =3; Recovered/ resolved with sequel =4; Fatal=5; Unknown =6.

**\*\*Seriousness criteria:** Death =1; Disability or permanent damage =2; Important Medical Event =3; Life threatening = 4; Congenital anomaly/Birth Defect =5; Hospitalization =6.

**\*\*\*Causality:** Possible =1; Not related =2; Not assessable =3; Not reported =4.

**Table 9: SUSPECT DRUG(S) INFORMATION**

Brand Name	Active Ingredient	Admin Route	Unit Dose	Frequency	Daily Dose	Start Date (DD-MMM-YYYY)	Stop Date (DD-MMM-YYYY)	Batch No.	Indication	Trimester Exposed*: (please use the legend below)	Action Taken**: (please use the legend below)

**\*Trimester Exposed:** Stopped before conception =0; First =1; Second =2; Third =3 (it may be more than one trimester)

**\*\*Action Taken:** Dosage maintained=1; Drug discontinued =2; Dose increased=3; Dose reduced=4; Not applicable=5; Unknown=6.

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**Table 10: CONCOMITANT/ PAST DRUG(s) DETAILS**

Brand name	Active ingredient	Dosing regimen	Start date	Stop date	Indication	Action Taken

**Table 11: NARRATIVE**

**Table 12: LINKED CASES (i.e. Child-Mother, Twins, for use by LSO)**