28 April 2010

Pregnancy Capture Form
Revlimid

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Pregnancy Capture Form Revlimid

Please complete this form to report a pregnancy in a patient (or in a female partner of a male patient) treated with lenalidomide. Please send immediately to Celgene. Contact details are given below.

As part of Celgene's Safety Monitoring System, it is essential that we follow-up on all reported pregnancies. Celgene will 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 regarding foetal exposure to lenalidomide.

1.

*2**. Drug Safety Europe, Celgene***

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INTIAL PREGNANCY REPORT FORM

REPORTER INFORMATION	
Reporter Name:	**Occupation:**
Address:	**City, Country:**
Phone No.: **Fax No.:**	**Email address:**

FEMALE PATIENT INFORMATION		
Patient ID:	**Age:**	**Date of Birth:**

FEMALE PARTNER OF MALE PATIENT		
ID:	**Age:**	**Date of Birth:**

PATIENT TREATMENT INFORMATION: LENALIDOMIDE CAPSULE			
Batch No.	**Expiry Date:**	**Dose:**	**Frequency:**
Start Date:		**Stop Date:**	
Indication for Use:			

FOLLOW-UP OF THE PREGNANCY		
	Yes	**No**
Has the patient already been referred to an Obtetrician/gynecologist		
If yes, please specify his/her name and contact details		

REASON FOR FAILURE OF PREGNANCY PREVENTION PROGRAMME		
	Yes	**No**
Was patient erroneously considered not to be of child bearing potential		
If yes, state reason for considering not to be of childbearing potential		
a. Age ≥ 50 years and naturally amenorrhoeic for ≥ 1 year		
b. Premature ovarian failure confirmed by a specialist gynaecologist		
c. Previous bilateral salpingo-oophorectomy, or hysterectomy		
d. XY genotype, Turner syndrome, uterine agenesis.		
Indicate from the list below what contraception was used	**Yes**	**No**
a. Implant		
b. Levonorgestrel-releasing intrauterine system (IUS)		
c. Medroxyprogesterone acetate depot		
d. Tubal sterilization (specify below)		
I. Tubal ligation		
II. Tubal diathermy		
III. Tubal clips		
e. Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses		
f. Ovulation inhibitory progesterone-only pills (i.e., desogestrel)		
g. Other progesterone-only pills		
h. Combined oral contraceptive pill		
i. Other intra-uterine devices		
j. Condoms		
k. Cervical cap		
l. Sponge		
m. Withdrawal		
n. Other		
o. None		
Indicate from the list below the reason for contraceptive failure	**Yes**	**No**
Missed oral contraception		
Other medication or intercurrent illness interacting with oral contraception		
Identified mishap with barrier method		

Unknown		
Had the patient committed to complete and continuous abstinence		
Was lenalidomide started despite patient already being pregnant		
Did patient receive educational materials on the potential risk of teratogenicity		
Did patient receive instructions on need to avoid pregnancy		

PRENATAL INFORMATION

Date of last menstrual period:	**Estimated Delivery Date:**

Pregnancy test	**reference range**	**Date**
Urine Qualitative		
Serum quantitative		

PAST OBSTRETRIC HISTORY

Year of pregnancy	**Outcome**					
	Spontaneous abortion	**Therapeutic abortion**	**Live birth**	**Still birth**	**Gestational Age**	**Type of delivery**

BIRTH DEFECTS

	Yes	**No**	**Unknown**
Was there any birth defect from any pregnancy			
Is there any family history of any congenital abnormality			
If yes to either of these questions, please provide details below			

MATERNAL PAST MEDICAL HISTORY				
Condition	**Dates**		**Treatment**	**Outcome**
	From	**To**		

MATERNAL CURRENT MEDICAL CONDITIONS		
Condition	**From**	**Treatment**

MATERNAL SOCIAL HISTORY		
	Yes	**No**
Alcohol		
If yes, amount/units per day:		

Tobacco		
If yes, amount per day:		
IV or recreational drug use		
If yes, provide details		

MATERNAL MEDICATION DURING PREGNANCY AND IN 4 WEEKS BEFORE PREGNANCY

(including herbal, alternative and over the counter medicines and dietary supplements)

Medication/treatment	Start Date	Stop Date/ Continuing	Indication

NAME OF PERSON COMPLETING THIS FORM	SIGNATURE	DATE