Pregnancy Reporting Form

Please complete this form to report a pregnancy in a patient (or in a female partner of a male patient) treated with lenalidomide.

As part of Rowex Ltd's Safety Monitoring System, it is essential that we follow-up on all reported pregnancies. Rowex Ltd. will therefore be in contact with you for further information in due course and would value your co-operation to ensure we are able to obtain all relevant information regarding fetal exposure to lenalidomide.

Please email immediately to Rowex Ltd. at the number/address below:

Rowex Ltd. Drug Safety: Tel: 027 50077 Rowex Ltd.
Email: pv@rowa-pharma.ie Bantry, Co. Cork.

Reporter's details		
Title: (Mr, Mrs, Miss, Dr., etc)	First Name(s):	Surname:
Job Title:		
Address:		
City, Town:	County:	
Post code:	Country:	
Phone Number:	Fax Number:	
Email address:		

Female Patient information		
Patient ID:	Age:	Date of birth: DD MM YYYY

Female partner or male patient information		
Patient ID:	Age:	Date of birth: DD MM YYYY

Exposure of a pregnant female - not patient or partner		
Patient ID:	Age:	Date of birth: DD MM YYYY

Patient treatment information: Lenalidomide capsule			
Batch No.:	Expiry Date:	Dose:	Frequency:
Start Date: DD MM YYYY	Stop Date: DD MM YYYY		
Indication for use:			

Menses information				
Date of last menses: DD MM YYYY	Regular menses: No?	TICK	Regular menses: Yes?	TICK

Pregnancy information				
Has the pregnancy been confirmed?	No?	TICK	Yes?	TICK
Estimated gestational stage:	Estimated date of delivery: DD MM YYYY			
Has the patient already been referred to an obstetrician/gynecologist?	No?	TICK	Yes?	TICK

If yes, please specify his/her name and contact details

Name:	Contact:
Reporter	
Signature:	Date: DD MM YYYY

Background Information on Reason for Pregnancy

	YES	NO
Was patient erroneously considered not to be of child bearing potential	TICK	TICK
If yes, state reason for considering not to be of childbearing potential	TICK	TICK
a. Age ≥ 50 years and naturally amenorrheic* for ≥ 1 year *amenorrhea following cancer therapy or during lactation does not rule out childbearing potential	TICK	TICK
b. Premature ovarian failure confirmed by a specialist gynecologist	TICK	TICK
c. Previous bilateral salpingo-oophorectomy, or hysterectomy	TICK	TICK
d. XY genotype, Turner syndrome, uterine agenesis.	TICK	TICK

Indicate from the list below what contraception was used		
a. Implant	TICK	TICK
b. Levonorgestrel-releasing intrauterine system (IUS)	TICK	TICK
c. Medroxyprogesterone acetate depot	TICK	TICK
d. Tubal sterilization (specify below)	TICK	TICK
I. Tubal ligation	TICK	TICK
II.Tubal diathermy	TICK	TICK
III. Tubal clips	TICK	TICK
e. Sexual intercourse with a vasectomized male partner only; vasectomy must be confirmed by two negative semen analyses	TICK	TICK
f. Ovulation inhibitory progesterone-only pills (i.e., desogestrel)	TICK	TICK
g. Other progesterone-only pills	TICK	TICK
h. Combined oral contraceptive pill	TICK	TICK
i. Other intra-uterine devices	TICK	TICK
j. Condoms	TICK	TICK
k. Cervical cap	TICK	TICK
l. Sponge	TICK	TICK
m.Withdrawal	TICK	TICK
n. Other	TICK	TICK
o. None	TICK	TICK

Indicate from the list below the reason for contraceptive failure		
Missed oral contraception	TICK	TICK
Other medication or intercurrent illness interacting with oral contraception	TICK	TICK
Identified mishap with barrier method	TICK	TICK
Unknown	TICK	TICK
Had the patient committed to complete and continuous abstinence	TICK	TICK
Was lenalidomide started despite patient already being pregnant	TICK	TICK
Did patient receive educational materials on the potential risk of teratogenicity	TICK	TICK
Did patient receive instructions on need to avoid pregnancy	TICK	TICK

Prenatal information		
Date of last menstrual period: DD MM YYYY	Estimated Delivery Date: DD MM YYYY	
PREGNANCY TEST	REFERENCE RANGE	DATE
Urine Qualitative:		DD MM YYYY
Serum Quantitative:		DD MM YYYY

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 abstinence			
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	TICK	TICK
If yes, amount/units per day:		
Tobacco	TICK	TICK
If yes, amount per day:		
IV or recreational drug use	TICK	TICK
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

Data Privacy statement:
All personal information will be strictly confidential and not used for any other purposes than preparing a report form.