

Pomalidomide Krka (pomalidomide) Pregnancy Reporting Form

This Pregnancy Reporting Form must be completed for each female patient or female partner of a male patient who experienced pregnancy during therapy with pomalidomide.

Pregnancy Reporting Form must be sent to KRKA, d.d., Novo mesto IMMEDIATELY. Please see contact details below.

KRKA, d.d., Novo mesto may contact you in order to gather additional information regarding foetal exposure to pomalidomide.

KRKA, d.d., Novo mesto
 Telephone: +353 1 413 3710
 Email: pharmacovigilance.IE@krka.biz

Reporter's Information		
Reporter's Name:	Reporter's Profession:	
Telephone number:	Email:	
Address:	Date of awareness: DD MM YYYY	
Patient and therapy Information		
Pregnant Woman's Initials (patient or female partner of a male patient receiving pomalidomide):	Date of Birth: DD MM YYYY	Age:
Please select one of the options below:		
<input type="checkbox"/> Pregnancy of Patient	<input type="checkbox"/> Pregnancy of Patient's Partner	<input type="checkbox"/> Exposure of a Pregnant Female
Drug Name:		
Batch Number:	Shelf life:	Daily dosage: Frequency:
Date of First Dose: DD MM YYYY	Date of Last Dose: DD MM YYYY	
Indication:		
Pregnancy test	Reference Range:	Date DD MM YYYY
<input type="checkbox"/> Urine Qualitative		
<input type="checkbox"/> Serum Quantitative		
Date of Last Menstrual Period:		
Female is Currently: weeks pregnant	No Longer Pregnant	Unknown
Female has elected to	Carry Pregnancy to Term	Estimated Delivery Date: DD MM YYYY
	Terminate Pregnancy	Date Performed or Pending: DD MM YYYY
Patient's Prescriber's Information:		
Prescriber Name:	Date: DD MM YYYY	
Address:	Email:	
Phone number:	Fax:	
Name of the person completing this form	Signature	Date DD MM YYYY

Background Information on Reason for Pregnancy						
Was patient erroneously considered not to be of childbearing potential?	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO		
If yes, state reason for considering not to be of childbearing potential						
• Age ≥ 50 years and naturally amenorrhoeic* for ≥ 1 year *amenorrhoea following cancer therapy or during breast-feeding does not rule out childbearing potential	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO		
• Premature ovarian failure confirmed by a specialist gynaecologist	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO		
• Previous bilateral salpingo-oophorectomy, or hysterectomy	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO		
• XY genotype, Turner syndrome, uterine agenesis	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO		
Indicate from the list below what contraception was used						
• Implant	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO		
• Levonorgestrel-releasing intrauterine system (IUS)	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO		
• Medroxyprogesterone acetate depot	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO		
• Tubal sterilisation (specify below)	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO		
○ Tubal ligation	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO		
○ Tubal diathermy	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO		
○ Tubal chips	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO		
• Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO		
• Ovulation inhibitory progesterone-only pills (i.e. desogestrel)	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO		
• Other progesterone-only pills	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO		
• Combined oral contraceptive pill	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO		
• Other intra-uterine devices	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO		
• Condoms	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO		
• Cervical cap	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO		
• Sponge	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO		
• Withdrawal	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO		
• Other	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO		
• None	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO		
Indicate from the list below the reason for contraceptive failure						
• Missed oral contraception	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO		
• Other medication or intercurrent illness interacting with oral contraception	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO		
• Identified mishap with barrier method	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO		
• Unknown	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO		
• Had the patient committed to complete and continuous abstinence	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO		
• Was the drug started despite patient already being pregnant	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO		
• Did patient receive educational materials on the potential risk of teratogenicity	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO		
• Did patient receive instructions on need to avoid pregnancy	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO		
Prenatal Information						
Date of Last Menstrual Period: DD MM YYYY		Estimated Delivery Date: DD MM YYYY				
Pregnancy test						
<input type="checkbox"/> Urine Qualitative	Reference Range:	Date: DD MM YYYY				
<input type="checkbox"/> Serum Quantitative	Reference Range:	Date: DD MM YYYY				
Past Obstetric History						
Year of Pregnancy	Outcome				Gestational Age	Type of Delivery
Y Y Y Y	<input type="checkbox"/> Spontaneous abortion	<input type="checkbox"/> Therapeutic abortion	<input type="checkbox"/> Live birth	<input type="checkbox"/> Still birth		
Y Y Y Y	<input type="checkbox"/> Spontaneous abortion	<input type="checkbox"/> Therapeutic abortion	<input type="checkbox"/> Live birth	<input type="checkbox"/> Still birth		
Y Y Y Y	<input type="checkbox"/> Spontaneous abortion	<input type="checkbox"/> Therapeutic abortion	<input type="checkbox"/> Live birth	<input type="checkbox"/> Still birth		
Y Y Y Y	<input type="checkbox"/> Spontaneous abortion	<input type="checkbox"/> Therapeutic abortion	<input type="checkbox"/> Live birth	<input type="checkbox"/> Still birth		
Y Y Y Y	<input type="checkbox"/> Spontaneous abortion	<input type="checkbox"/> Therapeutic abortion	<input type="checkbox"/> Live birth	<input type="checkbox"/> Still birth		
Birth defects						
Was there any birth defect from any pregnancy?	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>	UNKNOWN
Is there any family history of any congenital abnormality abstinence?	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>	UNKNOWN
If yes to either of these questions, please provide details below:						

