IRELAND
Version 5.0

Imnovid®▼ (pomalidomide)
Pregnancy Report Form

Pregnancy reports must be sent to Bristol-Myers Squibb (BMS) Medical Information IMMEDIATELY
This form must be returned to BMS Medical Information
Tel: 1800 749 749 - Email: medical.information@bms.com

NOTE: Please use the first three letters of the month (e.g. JAN)

Date of awareness: D D M O N Y Y Y Y

Patient Data

Sex of Patient: ○ Female ○ Male

○ Pregnancy of Patient
○ Pregnancy of Patient's Partner **OR**
○ Exposure of a Pregnant Female (complete information below)

Pregnant Woman's Initials (F, M, L): | Date of Birth: D D M O N Y Y Y Y | Age:

Patient Initials (F, M, L): (Who received drug) | Date of Birth: D D M O N Y Y Y Y | Age:

Drug Name:

Date of First Dose: D D M O N Y Y Y Y | Date of Last Dose: D D M O N Y Y Y Y

Pregnancy Initially Diagnosed By:

○ Home Urine Test
○ Office Urine Test
○ Serum Test

Date of Pregnancy Test: D D M O N Y Y Y Y | Last Menstrual Period: D D M O N Y Y Y Y

Female is Currently: ____ weeks pregnant **OR** ○ No longer Pregnant ○ Unknown

Female has Elected to: ○ Carry Pregnancy to Term | Expected Date of Delivery: D D M O N Y Y Y Y
○ Terminate Pregnancy | Date Performed or Pending: D D M O N Y Y Y Y

Reporter's Information:

Reporter's Name: | Date: D D M O N Y Y Y Y

Reporter's Contact Information/ Address: | Reporter's Signature:

Reporter's Phone Number:

Reporter's Email Address: | Reporter's Fax Number:

Patient's Prescriber's Information:

Prescriber's Name: | Date: D D M O N Y Y Y Y

Prescriber's Contact Information/ Address: | Prescriber's Signature:

Prescriber's Phone Number:

Prescriber's Email Address: | Prescriber's Fax Number:

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Background Information on Reason for Pregnancy

Was patient erroneously considered not to be of childbearing potential?	○ Yes	○ 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 breastfeeding does not rule out childbearing potential.	○ Yes	○ No
• Premature ovarian failure confirmed by a specialist gynaecologist.	○ Yes	○ No
• Previous bilateral salpingo-oophorectomy, or hysterectomy.	○ Yes	○ No
• XY genotype, Turner syndrome, uterine agenesis.	○ Yes	○ No
Indicate from the list below what contraception was used		
• Implant	○ Yes	○ No
• Levonorgestrel-releasing intrauterine system (IUS)	○ Yes	○ No
• Medroxyprogesterone acetate depot	○ Yes	○ No
• Tubal sterilisation (specify below)	○ Yes	○ No
○ Tubal ligation	○ Yes	○ No
○ Tubal diathermy	○ Yes	○ No
○ Tubal chips	○ Yes	○ No
• Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses.	○ Yes	○ No
• Ovulation inhibitory progesterone-only pills (i.e. desogestrel)	○ Yes	○ No
• Other progesterone-only pills	○ Yes	○ No
• Combined oral contraceptive pill	○ Yes	○ No
• Other intra-uterine devices	○ Yes	○ No
• Condoms	○ Yes	○ No
• Cervical cap	○ Yes	○ No
• Sponge	○ Yes	○ No
• Withdrawal	○ Yes	○ No
• Other	○ Yes	○ No
• None	○ Yes	○ No
Indicate from the list below the reason for contraceptive failure		
• Missed oral contraception.	○ Yes	○ No
• Other medication or intercurrent illness interacting with oral contraception.	○ Yes	○ No
• Identified mishap with barrier method.	○ Yes	○ No
• Unknown	○ Yes	○ No
• Had the patient committed to complete and continuous abstinence.	○ Yes	○ No
• Was the drug started despite patient already being pregnant.	○ Yes	○ No
• Did patient receive educational materials on the potential risk of teratogenicity.	○ Yes	○ No
• Did patient receive instructions on need to avoid pregnancy.	○ Yes	○ No

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Background Information on Reason for Pregnancy

Prenatal information

Date of Last Menstrual Period: D D M O N Y Y Y Y

Estimated Delivery Date: D D M O N Y Y Y Y

Pregnancy test

Urine Qualitative ◯	Reference Range:		Date: D D M O N Y Y Y Y
Serum Quantitative ◯	Reference Range:		Date: D D M O N Y Y Y Y

Past Obstetric History

Year of Pregnancy	Outcome				Gestational Age	Type of Delivery
Y Y Y Y	◯ Spontaneous abortion	◯ Therapeutic abortion	◯ Live birth	◯ Still birth		
Y Y Y Y	◯ Spontaneous abortion	◯ Therapeutic abortion	◯ Live birth	◯ Still birth		
Y Y Y Y	◯ Spontaneous abortion	◯ Therapeutic abortion	◯ Live birth	◯ Still birth		
Y Y Y Y	◯ Spontaneous abortion	◯ Therapeutic abortion	◯ Live birth	◯ Still birth		
Y Y Y Y	◯ Spontaneous abortion	◯ Therapeutic abortion	◯ Live birth	◯ Still birth		

Birth defects

Was there any birth defect from any pregnancy?	◯ Yes	◯ No	◯ Unknown
Is there any family history of any congenital abnormality abstinence?	◯ Yes	◯ No	◯ Unknown

If yes to either of these questions, please provide details below:

Maternal Past Medical History

Condition	Dates	Treatment	Outcome
	From: D D M O N Y Y Y Y To: D D M O N Y Y Y Y		
	From: D D M O N Y Y Y Y To: D D M O N Y Y Y Y		
	From: D D M O N Y Y Y Y To: D D M O N Y Y Y Y		
	From: D D M O N Y Y Y Y To: D D M O N Y Y Y Y		
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Maternal Current Medical Conditions

Condition	From	Treatment
	D D M O N Y Y Y Y	
	D D M O N Y Y Y Y	
	D D M O N Y Y Y Y	
	D D M O N Y Y Y Y	
	D D M O N Y Y Y Y	
	D D M O N Y Y Y Y	
	D D M O N Y Y Y Y	

Maternal Social History

Alcohol ◯ Yes ◯ No
If yes, amount/units per day:

Tobacco ◯ Yes ◯ No
If yes, amount per day:

IV or recreational drug use ◯ Yes ◯ No
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	Dates	Indication
	Start Date: D D M O N Y Y Y Y Stop Date/Continuing: D D M O N Y Y Y Y	
	Start Date: D D M O N Y Y Y Y Stop Date/Continuing: D D M O N Y Y Y Y	
	Start Date: D D M O N Y Y Y Y Stop Date/Continuing: D D M O N Y Y Y Y	
	Start Date: D D M O N Y Y Y Y Stop Date/Continuing: D D M O N Y Y Y Y	
	Start Date: D D M O N Y Y Y Y Stop Date/Continuing: D D M O N Y Y Y Y	
	Start Date: D D M O N Y Y Y Y Stop Date/Continuing: D D M O N Y Y Y Y	

Name of person completing this form

Name:

Date: D D M O N Y Y Y Y

Signature:

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Data Privacy Notice

Your personal data will be processed by Bristol-Myers Squibb Pharma EEIG (hereinafter "BMS"), for the purposes of complying with its drug safety legal obligations and for storage purposes.

BMS may share your data with other BMS entities and third parties providing services to BMS. This may entail the transfer of your data to other countries such as the USA and India. When such countries do not provide an equivalent level of protection to personal data as your country, BMS will implement appropriate legal, organisational, and technical security measures to protect your information from unauthorised access, use or disclosure, including the use of standard data protection clauses and Binding Corporate Rules. BMS will retain your personal data for the length of time required by law.

You have the right to access and verify your personal information held by BMS, receive a copy of it, obtain its correction and deletion if it is inaccurate and object to certain processing.

For the exercise of your rights and for any questions regarding data protection you can contact our Data Protection Officer: eudpo@bms.com. If you are unhappy about how BMS is processing your personal data, you have the right to lodge a complaint with the supervisory authority.

Reporter's Signature (required):

Signature:	Date signed: D D M O N Y Y Y Y

On behalf of BMS, thank you for providing information that will assist us in our commitment to patient safety.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.

Bristol Myers Squibb™