

UK

Pregnancy reports for Revlimid must be sent to Bristol-Myers Squibb (BMS) Medical Information IMMEDIATELY

This form must be returned to BMS Medical Information:
Phone: 0800 731 1736, 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
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Patient Data

Sex of Patient:	<input type="radio"/> Female	<input type="radio"/> Male
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- 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:	
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Patient Initials (F, M, L): (Who received drug)				Date of Birth:	D	D	M	O	N	Y	Y	Y	Y	Age:	
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Drug Name:	
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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
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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
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Female is Currently: weeks pregnant **OR** No longer Pregnant Unknown

Female has Elected to:	<input type="radio"/> Carry Pregnancy to Term	Expected Date of Delivery:	D	D	M	O	N	Y	Y	Y	Y
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<input type="radio"/> Terminate Pregnancy	Date Performed or Pending:	D	D	M	O	N	Y	Y	Y	Y
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Reporter's Information:

Reporter's Name:		Date:	D	D	M	O	N	Y	Y	Y	Y
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Reporter's Contact Information/ Address:		Reporter's Signature:	
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- GB
- Northern Ireland

Reporter's Email Address:		Reporter's Phone Number:	
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		Reporter's Fax Number:	
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Patient's Prescribing Physician's Information:

Physician's Name:		Date:	D	D	M	O	N	Y	Y	Y	Y
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Physician's Contact Information/ Address:		Physician's Signature:	
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- GB
- Northern Ireland

Physician's Email Address:		Physician's Phone 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 sexual 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
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 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			
<table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td>Y</td><td>Y</td><td>Y</td><td>Y</td></tr></table> <input type="radio"/> Spontaneous abortion	Y	Y	Y	Y	<input type="radio"/> Therapeutic abortion	<input type="radio"/> Live birth	<input type="radio"/> Still birth	<input type="text"/>	<input type="text"/>
Y	Y	Y	Y						
<table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td>Y</td><td>Y</td><td>Y</td><td>Y</td></tr></table> <input type="radio"/> Spontaneous abortion	Y	Y	Y	Y	<input type="radio"/> Therapeutic abortion	<input type="radio"/> Live birth	<input type="radio"/> Still birth	<input type="text"/>	<input type="text"/>
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Y	Y	Y	Y						

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: <table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td>D</td><td>D</td><td>M</td><td>O</td><td>N</td><td>Y</td><td>Y</td><td>Y</td><td>Y</td></tr></table> To: <table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td>D</td><td>D</td><td>M</td><td>O</td><td>N</td><td>Y</td><td>Y</td><td>Y</td><td>Y</td></tr></table>	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													
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Maternal Current Medical Conditions												
Condition	From										Treatment	
	D	D	M	O	N	Y	Y	Y	Y	Y		
	D	D	M	O	N	Y	Y	Y	Y	Y		
	D	D	M	O	N	Y	Y	Y	Y	Y		
	D	D	M	O	N	Y	Y	Y	Y	Y		
	D	D	M	O	N	Y	Y	Y	Y	Y		
	D	D	M	O	N	Y	Y	Y	Y	Y		
	D	D	M	O	N	Y	Y	Y	Y	Y		
	D	D	M	O	N	Y	Y	Y	Y	Y		

Maternal Social History												
Alcohol	<input type="radio"/> Yes	<input type="radio"/> No	Tobacco	<input type="radio"/> Yes	<input type="radio"/> No	IV or recreational drug use	<input type="radio"/> Yes	<input type="radio"/> No				
If yes, amount/units per day:			If yes, amount per day:			If yes, provide details:						
<input type="text"/>			<input type="text"/>			<input type="text"/>						

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		

Name of person completing this form												
Name:										Signature:		
Date:	D	D	M	O	N	Y	Y	Y	Y			

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Data Privacy Notice

Your personal data will be processed by Bristol-Myers Squibb Pharma EEIG (hereinafter "BMS"), as marketing authorisation holder of pharmaceutical products and its worldwide Affiliates, to the extent and for as long as necessary, for the purposes of the compliance with drug safety legal obligations and for storage purposes.

To conduct risk management programme activities, we may use third party service providers, who will handle directly any reporting relating to pregnancy, acting on our behalf, and upon our prior instructions.

BMS may disclose your personal information to regulatory authorities, affiliates of the BMS Group, service providers or other collaborators. Some of these entities may be located outside of the UK. BMS will take appropriate measures, such as implementing standard data protection clauses, to ensure that your personal information will be kept secure in accordance with applicable data protection law. BMS will only retain your personal data for the length of time required by law.

Under applicable law, you may 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. If you wish to exercise those rights, you can contact our data protection officer at: eudpo@bms.com. You may also have the right to lodge a complaint with the supervisory authority enforcing data protection by visiting this URL: <https://ico.org.uk/>

Reporter's Signature (required):

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

