

UK

**Pregnancy reports 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:  Carry Pregnancy to Term  Terminate Pregnancy

Expected Date of Delivery:	D	D	M	O	N	Y	Y	Y	Y
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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: <input type="radio"/> GB <input type="radio"/> Northern Ireland		Reporter's Signature:	
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Reporter's Phone Number:	
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Reporter's Email Address:		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: <input type="radio"/> GB <input type="radio"/> Northern Ireland		Physician's Signature:	
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Physician's Phone Number:	
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Physician's Email Address:		Physician'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:  Estimated Delivery Date:

**Pregnancy test**

Urine Qualitative  Reference Range:  Date:

Serum Quantitative  Reference Range:  Date:

**Past Obstetric History**

Year of Pregnancy	Outcome	Gestational Age	Type of Delivery
<input type="text" value="Y Y Y Y"/>	<input type="radio"/> Spontaneous abortion <input type="radio"/> Therapeutic abortion <input type="radio"/> Live birth <input type="radio"/> Still birth	<input type="text"/>	<input type="text"/>
<input type="text" value="Y Y Y Y"/>	<input type="radio"/> Spontaneous abortion <input type="radio"/> Therapeutic abortion <input type="radio"/> Live birth <input type="radio"/> Still birth	<input type="text"/>	<input type="text"/>
<input type="text" value="Y Y Y Y"/>	<input type="radio"/> Spontaneous abortion <input type="radio"/> Therapeutic abortion <input type="radio"/> Live birth <input type="radio"/> Still birth	<input type="text"/>	<input type="text"/>
<input type="text" value="Y Y Y Y"/>	<input type="radio"/> Spontaneous abortion <input type="radio"/> Therapeutic abortion <input type="radio"/> Live birth <input type="radio"/> Still birth	<input type="text"/>	<input type="text"/>
<input type="text" value="Y Y Y Y"/>	<input type="radio"/> Spontaneous abortion <input type="radio"/> Therapeutic abortion <input type="radio"/> Live birth <input type="radio"/> Still birth	<input type="text"/>	<input type="text"/>

**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: <input type="text" value="D D M O N Y Y Y Y"/> To: <input type="text" value="D D M O N Y Y Y Y"/>		
	From: <input type="text" value="D D M O N Y Y Y Y"/> To: <input type="text" value="D D M O N Y Y Y Y"/>		
	From: <input type="text" value="D D M O N Y Y Y Y"/> To: <input type="text" value="D D M O N Y Y Y Y"/>		
	From: <input type="text" value="D D M O N Y Y Y Y"/> To: <input type="text" value="D D M O N Y Y Y Y"/>		
	From: <input type="text" value="D D M O N Y Y Y Y"/> To: <input type="text" value="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  Yes  No Tobacco  Yes  No IV or recreational drug use  Yes  No

If yes, amount/units per day:  If yes, amount per day:  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 Y Stop Date/Continuing: D D M O N Y Y Y Y Y	
	Start Date: D D M O N Y Y Y Y Y Stop Date/Continuing: D D M O N Y Y Y Y Y	
	Start Date: D D M O N Y Y Y Y Y Stop Date/Continuing: D D M O N Y Y Y Y Y	
	Start Date: D D M O N Y Y Y Y Y Stop Date/Continuing: D D M O N Y Y Y Y Y	
	Start Date: D D M O N Y Y Y Y Y Stop Date/Continuing: D D M O N Y Y Y Y Y	
	Start Date: D D M O N Y Y Y Y Y Stop Date/Continuing: D D M O N Y Y Y Y Y	

**Name of person completing this form**

Name:  Signature:

Date:  D D M O N Y 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 program 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](mailto: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.