

Pregnancy reports must be sent to the relevant Medical information team IMMEDIATELY

This form must be returned to the MAH who provided the product. Please see contact details below:

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 E-mail Address:	

Patient's Prescribing Physician's Information:

Physician's Name:	Date: D D M O N Y Y Y Y
Physician's Contact Information/ Address:	Physician's Signature:
	Physician's Phone Number:
Physician's E-mail 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 \geq 50 years and naturally amenorrhoeic* for \geq 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 sterilization (specify below) Yes No
 - Tubal ligation Yes No
 - Tubal diathermy Yes No
 - Tubal chips Yes No
- Sexual intercourse with a vasectomized 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 | Expected 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	<input type="radio"/> Spontaneous abortion <input type="radio"/> Therapeutic abortion <input type="radio"/> Live birth <input type="radio"/> Still birth		
Y Y Y Y	<input type="radio"/> Spontaneous abortion <input type="radio"/> Therapeutic abortion <input type="radio"/> Live birth <input type="radio"/> Still birth		
Y Y Y Y	<input type="radio"/> Spontaneous abortion <input type="radio"/> Therapeutic abortion <input type="radio"/> Live birth <input type="radio"/> Still birth		
Y Y Y Y	<input type="radio"/> Spontaneous abortion <input type="radio"/> Therapeutic abortion <input type="radio"/> Live birth <input type="radio"/> Still birth		
Y Y Y Y	<input type="radio"/> Spontaneous abortion <input type="radio"/> Therapeutic abortion <input type="radio"/> Live birth <input type="radio"/> 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		
	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	<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 style="width: 100%;" type="text"/>		<input style="width: 100%;" type="text"/>		<input style="width: 100%;" 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: <table style="display: inline-table; border-collapse: collapse;"><tr><td style="border: 1px solid black; width: 20px; text-align: center;">D</td><td style="border: 1px solid black; width: 20px; text-align: center;">D</td><td style="border: 1px solid black; width: 20px; text-align: center;">M</td><td style="border: 1px solid black; width: 20px; text-align: center;">O</td><td style="border: 1px solid black; width: 20px; text-align: center;">N</td><td style="border: 1px solid black; width: 20px; text-align: center;">Y</td><td style="border: 1px solid black; width: 20px; text-align: center;">Y</td><td style="border: 1px solid black; width: 20px; text-align: center;">Y</td><td style="border: 1px solid black; width: 20px; text-align: center;">Y</td></tr></table>	D	D	M	O	N	Y	Y	Y	Y	
D	D	M	O	N	Y	Y	Y	Y		

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Data Privacy Notice

Your personal data will be processed by the relevant marketing authorisation holder, 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. Should you have any queries in relation to the use of your personal data please contact the relevant marketing authorisation holder.

Reporter's Signature (required):

Signature:

Date signed:

	D		D		M		O		N		Y		Y		Y		Y
--	---	--	---	--	---	--	---	--	---	--	---	--	---	--	---	--	---

Thank you for providing information that will assist us in our commitment to patient safety.