Ireland

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

The form must be returned to the Marketing Authorisation Holder (MAH) who provided the product. Please see the relevant MAH details below:

- Accord Healthcare Ireland Ltd. Email: medinfo@accord-healthcare.com Tel: 0044 1271 385257
- AS Grindeks Email: adrian.curley@grindeks.ie Tel: +353 (0)87 298 8226
- Teva Pharmaceuticals Ireland Email: medinfo@tevauk.com Tel: 0044 207 540 7117

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:		

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 E-mail 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	◯ 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	◯ 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		
	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
	DD MON YYYY	
	DD MON YYYY	
	DD MON YYYY	
	DD MON YYYY	
	DD MON YYYY	
	DD MON YYYY	
	DD MON YYYY	

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:	DD MON YYYY	
	Stop Date/Continuing:	DD MON YYYY	
	Start Date:	DD MON YYYY	
	Stop Date/Continuing:	DD MON YYYY	
	Start Date:	DD MON YYYY	
	Stop Date/Continuing:	DD MON YYYY	
	Start Date:	DD MON YYYY	
	Stop Date/Continuing:	DD MON YYYY	
	Start Date:	DD MON YYYY	
	Stop Date/Continuing:	DD MON YYYY	
	Start Date:	DD MON YYYY	
	Stop Date/Continuing:	DD MON YYYY	

Name of person completing this form

Name:

Date: DD MON YYYY

Signature:

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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

On behalf of Accord Healthcare Ireland Ltd. AS Grindeks and Teva Pharmaceuticals Ireland, thank you for providing information that will assist us in our commitment to patient safety.

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