

Pregnancy reports must be sent to Rowex Ltd. Medical Information IMMEDIATELY

This form must be returned to Rowex Ltd. Medical Information
Tel: 027-50077 - Email: pv@rowa-pharma.ie

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 Terminate Pregnancy

Expected Date of Delivery:

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

Date Performed or Pending:

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

Reporter's Information:

Reporter's Name:	Date: <table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td style="width: 20px; height: 20px; text-align: center;">D</td><td style="width: 20px; height: 20px; text-align: center;">D</td><td style="width: 20px; height: 20px; text-align: center;">M</td><td style="width: 20px; height: 20px; text-align: center;">O</td><td style="width: 20px; height: 20px; text-align: center;">N</td><td style="width: 20px; height: 20px; text-align: center;">Y</td><td style="width: 20px; height: 20px; text-align: center;">Y</td><td style="width: 20px; height: 20px; text-align: center;">Y</td><td style="width: 20px; height: 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		
Reporter's Contact Information/ Address:	Reporter's Signature:									
Reporter's Email Address:	Reporter's Phone Number:									
	Reporter's Fax Number:									

Patient's Prescriber's Information:

Prescriber's Name:	Date: <table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td style="width: 20px; height: 20px; text-align: center;">D</td><td style="width: 20px; height: 20px; text-align: center;">D</td><td style="width: 20px; height: 20px; text-align: center;">M</td><td style="width: 20px; height: 20px; text-align: center;">O</td><td style="width: 20px; height: 20px; text-align: center;">N</td><td style="width: 20px; height: 20px; text-align: center;">Y</td><td style="width: 20px; height: 20px; text-align: center;">Y</td><td style="width: 20px; height: 20px; text-align: center;">Y</td><td style="width: 20px; height: 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		
Prescriber's Contact Information/ Address:	Prescriber's Signature:									
Prescriber's Email Address:	Prescriber's Phone Number:									
	Prescriber's Fax Number:									

Pregnancy reports must be sent to Rowex Ltd. Medical Information IMMEDIATELY

This form must be returned to Rowex Ltd. Medical Information
Tel: 027-50077 - Email: pv@rowa-pharma.ie

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

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

Pregnancy reports must be sent to Rowex Ltd. Medical Information IMMEDIATELY

This form must be returned to Rowex Ltd. Medical Information
Tel: 027-50077 - Email: pv@rowa-pharma.ie

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

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 <input type="radio"/>	Reference Range:	Date:	D	D	M	O	N	Y	Y	Y	Y
Serum Quantitative <input type="radio"/>	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 Y To: D D M O N Y Y Y Y Y		
	From: D D M O N Y Y Y Y Y To: D D M O N Y Y Y Y Y		
	From: D D M O N Y Y Y Y Y To: D D M O N Y Y Y Y Y		
	From: D D M O N Y Y Y Y Y To: D D M O N Y Y Y Y Y		
	From: D D M O N Y Y Y Y Y To: D D M O N Y Y Y Y Y		

Pregnancy reports must be sent to Rowex Ltd. Medical Information IMMEDIATELY

This form must be returned to Rowex Ltd. Medical Information

Tel: 027-50077 - Email: pv@rowa-pharma.ie

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

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, providedetails:

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:

Pregnancy reports must be sent to Rowex Ltd. Medical Information IMMEDIATELY

This form must be returned to Rowex Ltd. Medical Information
Tel: 027-50077 - Email: pv@rowa-pharma.ie

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

Data Privacy Notice

Your personal data will be processed by Rowex Ltd., for the purposes of complying with its drug safety legal obligations and for storage purposes.

Rowex Ltd. may share your data with other Rowex Ltd. entities and third parties providing services to Rowex Ltd. 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, Rowex Ltd. 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. Rowex Ltd. 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 Rowex Ltd., 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 Rowex Ltd. at pv@rowa-pharma.ie. If you are unhappy about how Rowex Ltd. 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 Rowex Ltd., thank you for providing information that will assist us in our commitment to patient safety.

