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

| NOTE: Please use the firm | st 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 | | | |
| O Pregnancy of Patient | | | | |
| O Pregnancy of Patient's I | Partner OR | | | |
| ○ Exposure of a Pregnant | Female (complete information b | elow) | | |
| Pregnant Woman's Initial | s (F, M, L): | Date of Birth: | D D M O N Y Y Y | Age: |
| Patient Initials (F, M, L): | (Who received drug) | Date of Birth: | | 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 Diagnose | d By: | | | |
| O Home Urine Test | | | | |
| Office Urine Test | | | | |
| ○ Serum Test | | | | |
| Date of Pregnancy Test: | DDMONYY | Y Y Last Menstrual Period: | D D M O N Y Y Y Y | |
| Female is Currently: |] weeks pregnant \mathbf{OR} \bigcirc No lo | nger 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: | | |
| Reporter's Informat | tion: | | | |

Reporter's Name: Date: D M V Y Y Y Reporter's Contact Information/ Address: Reporter's Signature: Image: Contact Signature:<

Patient's Prescribing Physician's Information:

| Physician's Name: | Date: | D | D | M | 0 | Ν | Y | Y | Y Y |
|---|---------------------------|---|---|---|---|---|---|---|-----|
| Physician's Contact Information/ Address: | Physician's Signature: | | | | | | | | |
| | Physician's Phone Number: | | | | | | | | |

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| Physician's E-mail Address: | | Physician's Fax Number: | |
|-----------------------------|--|-------------------------|--|
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| | | | |

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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 | O No |
| Previous bilateral salpingo-oophorectomy, or hysterectomy | ⊖ Yes | |
| • XY genotype, Turner syndrome, uterine agenesis. | ⊖ Yes | |
| ndicate from the list below what contraception was used | | |
| ● Implant | ⊖ Yes | O No |
| Levonorgestrel-releasing intrauterine system (IUS) | ⊖ Yes | \bigcirc No |
| Medroxyprogesterone acetate depot | ⊖ Yes | ⊖ No |
| Tubal sterilization (specify below) | ⊖ Yes | ⊖ No |
| Tubal ligation | ⊖ Yes | \bigcirc No |
| Tubal diathermy | \bigcirc Yes | \bigcirc No |
| ○ Tubal chips | \bigcirc Yes | \bigcirc 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 | \bigcirc No |
| ndicate 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 | |
| Had the patient committed to complete and continuous abstinence | ⊖ Yes | |
| Was the drug started despite patient already being pregnant | ⊖ Yes | |
| Did patient receive educational materials on the potential risk of teratogenicity | ⊖ Yes | O No |
| Did patient receive instructions on need to avoid pregnancy | ⊖ Yes | |
| | | |

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| Background Information o | n Reason f | for Pregnancy | | | | |
|--------------------------------------|---------------------------------------|---|---|-------------------|-----------------|------------------|
| Prenatal information | | | | | | |
| Date of Last Menstrual Period: | DD | MONYY | Y Y Exp | ected Delivery Da | ate: D | D M O N Y Y Y Y |
| Pregnancy test | | | | | | |
| Urine Qualitative | Reference R | Range | | | Date: D | |
| Serum Quantitative | Reference R | Range | | | Date: D | |
| Past Obstetric History | | | | | | |
| ear of Pregnancy Outcome | | | | | Gestational Age | Type of Delivery |
| | ous abortior | ∩ ◯ Therapeutic aborti | on O Live birt | h () Still birth | | |
| | | ∩ ⊖ Therapeutic aborti | | | | |
| | | ∩ ⊖ Therapeutic aborti | | | | |
| | | \bigcirc Therapeutic aborti | | | | |
| | | OTherapeutic abortion | | | | |
| | | | 0 | 0.000 | • · · · · | - |
| Birth defects | | | 0 | 0.44 | 0 | |
| Vas there any birth defect from any | | | ◯ Yes | - | | |
| s there any family history of any co | - | - | ⊖ Yes | O No | | |
| yes to either of these questions | , please prov | ide details below: | | | | |
| | | | | | | |
| | | | | | | |
| Maternal Past Medical His | tory | | | | | |
| Condition | Dates | | | Treatment | | Outcome |
| | From: | D D M O N Y | Y Y Y | | | |
| | | | Y Y Y | | | |
| | To: | | , , , | | | |
| | From: | | <u> </u> | | | |
| | | | Y Y Y Y Y Y Y Y Y | | | |
| | From: To: From: | D D M O N Y D D M O N Y D D M O N Y | | | | |
| | From: To: From: To: | D D M O N Y D D M O N Y D D M O N Y D D M O N Y D D M O N Y | | | | |
| | From: To: From: To: From: | D D M O N Y D D M O N Y D D M O N Y D D M O N Y D D M O N Y D D M O N Y D D M O N Y | Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y | | | |
| | From: To: From: To: | D D M O N Y D D M O N Y D D M O N Y D D M O N Y D D M O N Y | Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y | | | |

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| Maternal Current Medica | I Conditions | | | | | | | | | | | | | | | | | |
|-------------------------------|--------------------------------------|--------|-------|-------|------------|----------|--------|------------|----------|--------|-----|---------|-------------|-----------|-----|----|----|------|
| Condition | From | | | | | | | | Т | reatm | ent | | | | | | | |
| | ם מ | M | 0 | N | Y | Y | Y | Y | | | | | | | | | | |
| | | | 0 | N | Y | Y | Y | Y | | | | | | | | | | |
| | | | 0 | N | V | V | V | V | | | | | | | | | | |
| | | | 0 | N | V | V | V | V | - | | | | | | | | | |
| | | | 0 | N | I V | I V | I V | I V | - | | | | | | | | | |
| | | | - | N | T V | I | T V | T V | - | | | | | | | | | |
| | | M | 0 | N | Y V | Y V | Y V | Y V | - | | | | | | | | | |
| | | IVI | 0 | IN | Ŷ | Ŷ | Ŷ | Ŷ | | | | | | | | | | |
| Maternal Social History | | | | | | | | | | | | | | | | | | |
| Alcohol | ⊖Yes ⊖No Tobaco | :0 | | | | | | 0 | Yes | С | No | IV o | r recreatio | onal drug | use | ΟY | es | ⊖ No |
| If yes, amount/units per day: | lf yes, a | amou | int p | er d | ay: | | | | | | | lf ye | es, provid | de detai | ls: | | | |
| | | | | | | | | | | | | | | | | | | |
| Maternal mediaction duri | ing programou and in A | | oko | ho | for | | rog | non | 01/ | | | | | | | | | |
| Maternal medication duri | | | | | | | - | IIdII | Cy | | | | | | | | | |
| Medication/treatment | Dates | | | ary S | uppic | | 1113) | | | | In | dicatio | 20 | | | | | |
| | | | | | | | | | | | | uicain | | | | | | |
| | Start Date: Stop Date/Continuing: | D | D | M | 1 0 1 0 | | | Y Y V N | Y V V | | | | | | | | | |
| | Start Date: | | | | | | | | | | | | | | | | | |
| | Stop Date/Continuing: | D D | D | M | 1 0 1 0 | | | y y y y | Y Y | Y Y | | | | | | | | |
| | Start Date: | D | ם | M | | | | | | | _ | | | | | | | |
| | Stop Date/Continuing: | D | D | M | | | | r r Y Y | / Y | Y Y | | | | | | | | |
| | Start Date: | D | ת | M | | ٨ | | | / v | / V | - | | | | | | | |
| | Stop Date/Continuing: | D | D | M | 1 0 | A | | Y Y | / Y | Y Y | | | | | | | | |
| | Start Date: | D | D | M | 1 0 | Λ | | y) | / Y | / Y | | | | | | | | |
| | Stop Date/Continuing: | D | D | M | 1 0 | Λ | / | Y Y | / Y | Ý Y | | | | | | | | |
| | Start Date: | D | D | M | 1 0 | Λ | | ΥY | / Y | Y Y | | | | | | | | |
| | Stop Date/Continuing: | D | D | M | 1 0 | \wedge | / | Y Y | / Y | Ý Y | | | | | | | | |
| Name of person complete | ing this form | | | | | | | | | | | | | | | | | |
| Name: | | | | 5 | Signa | atur | e: | | | | | | | | | | | |
| Date: D | DMONYY | Y Y | | | | | | | | | | | | | | | | |

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| Reporter's Signature (required): | | | | | | | | | |
|----------------------------------|--------------|---|---|---|---|---|---|---|-----|
| Signature: | Date signed: | D | D | M | 0 | N | Y | Y | Y Y |
| | | | | | | | | | |

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