## PREGNANCY REPORT FORM

# Pregnancy Report Form

**RO-GNE: PREGNANCY REPORT FORM**

***FOR ROCHE USE ONLY***

| Roche Received Date (dd-MMM-yyyy): | Local No: | MCN: |
|---|---|---|
| Report Type: | Prospective ☐ | Retrospective ☐ |

**1. REPORTER INFORMATION** Initial ☐ Follow-up ☐

Reporter Name:

Type: ☐ Physician (Specialty) ☐ Pharmacist

☐ Consumer ☐ Other (Specify)

Contact Address: Telephone Number:

Fax Number:

Postal/Zip Code: E-mail:

**2. EXPOSED PARENT'S DETAILS**

Who was exposed: Father ☐ Mother ☐ Initials: Date of Birth: dd MMM M yyyy

Height: inch ☐ cm ☐ Age at Conception:

Weight: lb ☐ kg ☐ Postal Code (France only):

Ethnic origin: Black ☐ Caucasian ☐ Hispanic ☐ Asian ☐ Other ☐ (Specify):

**3. PRODUCT INFORMATION** (Enter all relevant medications taken before (up to 24 months for Erivedge® female treated patients), and during pregnancy or if the father exposed enter medications taken prior to conception or up to 2 months after the last dose of Erivedge®)

| | **Product Name** (Generic/Trade) | **Suspect** | **Lot/ Batch #** | **Time of Exposure** (× as applicable) | | | | | **Route** | **Strength and Formulation** (mg, cap, tab) |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Pre conception | Trimester 1 | Trimester 2 | Trimester 3 | Delivery | | |
| 1. | | ☐ | | ☐ | ☐ | ☐ | ☐ | ☐ | | |
| 2. | | ☐ | | ☐ | ☐ | ☐ | ☐ | ☐ | | |
| 3. | | ☐ | | ☐ | ☐ | ☐ | ☐ | ☐ | | |
| 4. | | ☐ | | ☐ | ☐ | ☐ | ☐ | ☐ | | |

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5. ☐ ☐ ☐ ☐ ☐ ☐ ☐

| | Dosage Regimen | Start Date (dd-MMM-yyyy) | Stop Date (dd-MMM-yyyy) | Ongoing | Indication for Use |
|---|---|---|---|---|---|
| 1. | | | | ☐ | |
| 2. | | | | ☐ | |
| 3. | | | | ☐ | |
| 4. | | | | ☐ | |
| 5. | | | | ☐ | |

**4. PREGNANCY INFORMATION**

LMP Date: last menstrual period. dd MMM yyyy Est ☐

Estimated Date of Delivery: dd MMM yyyy

Conception Date: dd MMM yyyy Est ☐

**5. MEDICAL HISTORY**

**Contraception** (may choose more than one)

| | | | |
|---|---|---|---|
| None | ☐ | Condom | ☐ |
| Contraceptive Medication | ☐ | Surgical Sterilization (Male) | ☐ |
| Diaphragm | ☐ | Surgical Sterilization (Female) | ☐ |
| IUD | ☐ | Withdrawal | ☐ |
| Infertility (Male) | ☐ | Rhythm | ☐ |
| Infertility (Female) | ☐ | Unknown | ☐ |

**Number of previous**

| | |
|---|---|
| Pregnancies | |
| Therapeutic Abortions | |
| Spontaneous Abortions | |
| Stillbirth | |
| Deliveries | |
| Babies born with defects | |

**Risk Factors/ Medical History**

| | |
|---|---|
| Unknown | ☐ |
| Alcohol | ☐ |
| **Allergies*** | ☐ |
| **Diabetes*** | ☐ |
| **Infection*** | ☐ |
| Smoking | ☐ |

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| | | |
|---|---|---|
| Spermicide | | Drug abuse ☐<br>Other/Relevant History **(*specify below)** ☐ |

**Details:** (include dates & outcome as applicable) _____

_____

**6. PREGNANCY OUTCOME**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Ongoing | ☐ | Ectopic pregnancy | ☐ | Spontaneous abortion | ☐ | Unknown | ☐ |
| Live birth | ☐ | Stillbirth | ☐ | Therapeutic abortion | ☐ | Lost to follow-up | ☐ |

Provide date if applicable: | | | | (dd / MMM / yyyy)

**7. RELEVANT LABORATORY TESTS/PROCEDURES PRE AND POST OUTCOME** (e.g. Amniocentesis, ultrasound)

| | **Tests** | **Results** Units and normal values if applicable | **Pending** | **Pre/Post Outcome?** | **Date** dd-MMM-yyyy |
|---|---|---|---|---|---|
| 1. | | | ☐ | Pre ☐ Post ☐ | |
| 2. | | | ☐ | Pre ☐ Post ☐ | |
| 3. | | | ☐ | Pre ☐ Post ☐ | |

**Further details:** _____

_____

**8. BIRTH OUTCOME**

**Infant/Fetal Outcome:**

Number of infants/fetuses | | (in the event of more than 1 infant/fetus, complete Infant Information sections 8-11 on a separate form)

Normal ☐

Abnormal (birth defects/congenital abnormalities and other events experienced by the fetus/baby) ☐ Specify _____

Unknown ☐

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Death ☐ Date: ____ ____ ____ (dd MMM yyyy) Cause of death: _____

Autopsy results: _____

**9. INFANT INFORMATION**

| Gender: | | Weight: | | Length: | | Head circumference: | |
|---|---|---|---|---|---|---|---|
| Male: ☐ | | ____ | lb ☐ | ____ | inch ☐ | ____ | inch ☐ |
| Female: ☐ | | ____ | kg ☐ | ____ | cm ☐ | ____ | cm ☐ |

Gestational Age at Delivery/Abortion ____ (weeks)

Apgar Scores 1 minute ____ 5 minutes ____ 10 minutes ____

Were there any unusual features about the pregnancy or its outcome?

Yes ☐ No ☐

If yes, specify _____

Follow-up examination of the child:

Date: ____ ____ ____ (dd MMM yyyy)

Findings: _____

Paediatrician (in case of referral); Name: _____

Address: _____ Telephone No: _____

Fax No: _____

E-mail:

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**10. RELEVANT LABORATORY TESTS/PROCEDURES FOR BABY/FETUS**

| | **Tests** | **Results** (unit and normal values if | **Pending** | **Date** dd-MMM-yyyy |
|---|---|---|---|---|
| 1. | | | | |
| 2. | | | | |
| 3. | | | | |
| 4. | | | | |

**11. ADDITIONAL INFORMATION** Continue on Optional Supplementary Form if necessary

**Reporter Signature:**

**Date** (dd-MMM-yyyy):

Contact name for further information on pregnancy: (if different from REPORTER)

Contact Address: _____

Telephone No: _____

Fax No: _____

Email: _____

If completed by Roche delegate, ensure the data completed reflects the reporter's opinion

**FOR ROCHE USE ONLY**

**Signature:** _____ **Date** (dd-MMM-yyyy): _____

**PRINT NAME:**

**RO-GNE: PREGNANCY REPORT FORM OPTIONAL SUPPLEMENTARY INFORMATION FORM**

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**ADDITIONAL INFORMATION (Optional):**

**Signature:** _____

**Date** (dd-MMM-yyyy):