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 ☐ 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

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

PRINT NAME:

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Report Type:	Prospective	Retrospective

ADDITIONAL INFORMATION (Optional):

Signature: _____

Date (dd-MMM-yyyy):