Teriflunomide Exposure in Pregnancy Form

Date: _____
Patient I.D.: _____
Country / Province: _____
Report Type:
☐ Initial
☐ Follow up

Exposure during pregnancy:
☐ Maternal
☐ Paternal

Paternal Information:

Date of Birth (DD-MMM-YYYY):
Age: _____**years**
Ethnicity: ☐ **Asian** ☐ **Black** ☐ **Caucasian** ☐ **Hispanic** ☐ **Other,specify:**
Weight: _____ ☐ **kgs** ☐ **lbs**
Height: _____ ☐ **cm** ☐ **in**
Rhesus Factor: _____

Medical History

Risk Factor	Yes	No	Risk Factor	Frequency			
				Never	Occasionally	Often	Previously /Quit
Hepatitis			Substance Abuse				
Hypertension			Alcohol				
Psychiatric Illness			Smoking				
Epilepsy							
Diabetes							
HIV							
Other Notable Health Disorders /Conditions:							

Please describe _____							

Maternal Information:

Date of Birth (DD-MMM-YYYY):
Age: _____years
Ethnicity: Asian Black Caucasian Hispanic Other, specify:
Weight: kgs lbs _____
Height: cm in _____
Rhesus Factor: ___

Medical History

Risk Factor	Yes	No	Risk Factor	Frequency			
				Never	Occasionally	Often	Previously /Quit
Hepatitis			Substance Abuse				
Hypertension			Alcohol				
Psychiatric Illness			Smoking				
Epilepsy							
Diabetes							
HIV							
Other Notable Health							

Disorders /Conditions							

Immunizations:

Immunization	Yes, Date (DD-MMM-YYYY):	No
Rubella		
Toxoplasmosis		
CMV		

Was a contraception method used? ☐ **Yes** ☐ **No** ☐ **Unknown**
If yes, please check type of contraception:

☐ **Oral contraception (type not known)** ☐ **Oral contraception (Progesterone)**
☐ **Contraceptive Implant** ☐ **Intra-uterine device**
☐ **Oral contraception (Oestrogen + Progesterone)**
☐ **Transdermal contraception** ☐ **Contraceptive injection**
☐ **Condom**

History of ☐ **normal or** ☐ **abnormal menstrual cycles**
History of infertility ☐ **Yes** ☐ **No**

First Day of Last Menstrual Period (LMP) (DD-MMM-YYYY): _____

Estimated Delivery Date (DD-MMM-YYYY): _____
Specify method of calculation: _____

☐ **LMP**
☐ **Ultrasound Date (DD-MMM-YYYY):**
☐ **Other, please specify:** _____

Did you become pregnant while on teriflunomide? ☐ **Yes** ☐ **No**
If you got pregnant while on teriflunomide, was accelerated elimination used? ☐ **Yes** ☐ **No**

Teriflunomide Dosage at conception:

Gestational Age at Last Dose:

Duration of Treatment with Product while Pregnant:

Did you become pregnant after teriflunomide discontinuation? ☐ **Yes** ☐ **No**
If yes, was accelerated elimination used? ☐ **Yes** ☐ **No**
If yes, did you become pregnant within 11 days of teriflunomide discontinuation? ☐ **Yes** ☐ **No**

If accelerated elimination was not used, did you become pregnant within 2 years of teriflunomide discontinuation? ☐ **Yes** ☐ **No**

PATIENT'S MEDICAL HISTORY (include information on familial disorders, known risk factors or conditions that may affect the outcome of the pregnancy e.g. alcohol, smoking, other substance consumption, hypertension, eclampsia, diabetes including gestational, infections during pregnancy, environmental or occupational exposure that may pose a risk factor):

PREVIOUS OBSTETRIC HISTORY - provide details on all previous pregnancies below, including abortion or stillbirth: _____

_____

Gestation Weeks at Delivery: _____

Outcome of the pregnancy including any previous maternal complications and previous fetal / neonatal abnormalities and type: _____

_____

Family History:

Is there any history of congenital abnormalities, children dying young, chromosomal abnormalities, developmental delays or hereditary diseases in paternal or maternal family? ☐ **Yes** ☐ **No** ☐ **Unknown**

If yes, please specify:

Blood relationship between parents? ☐ **Yes** ☐ **No** ☐ **Unknown**

(If yes, specify degree)

DRUG INFORMATION - please list all medications, including OTC medications, and dietary supplements taken prior to or during pregnancy

Drug Name	Daily Dose	Route	Treatment Dates		Indication	Week of pregnancy	
			Start (DD-MMM-YYYY):	Stop (DD-MMM-YYYY):		Start	Stop

Were administered drugs discontinued due to pregnancy? ☐ **Yes** ☐ **No**

If yes, which drugs? _____

PRENATAL TESTING:

Have any specific tests, e.g. amniocentesis, ultrasound, maternal serum AFP, chorionic villi sampling, fetal stress test, genetic screening or other been performed during the pregnancy so far?

☐ **Yes** ☐ **No** ☐ **Unknown**

If yes, please specify test date and results:

Test	Date: (DD-MMM-YYYY)	Results

PREGNANCY OUTCOME

Pregnancy Ongoing: ☐ **Yes** ☐ **No**

If yes, Gestational age: (weeks) _____
Number of embryos / foetus(es): _____

Last ultrasound scan date (DD-MMM-YYYY): _____
☐ **Normal** ☐ **Abnormal, please specify:** _____

Delivery Date: (DD-MMM-YYYY): _____

☐ **Vaginal** ☐ **Forceps/ventouse** ☐ **Caesarean section**

Status of amniotic fluid: ☐ **Clear** ☐ **Not clear**

Placenta: ☐ **Normal** ☐ **Abnormal**

Medications provided during delivery: ☐ **yes, please specify** _____ ☐ **No**

Delivery duration: _____

Maternal complications or problems related to birth: _____

Abortion
Date:

☐ **Therapeutic** ☐ **Elective** ☐ **Spontaneous**
Please, specify reason and any abnormalities (if known): _____

☐ **Unspecified: _____**

At week ___
Complication:

☐ **Mother died (DD-MMM-YYYY): _____**
☐ **Neonate died (DD-MMM-YYYY): _____**

MATERNAL PREGNANCY ASSOCIATED EVENTS:
If the mother experienced an adverse drug reaction during pregnancy, please complete a data collection form and submit as requested to the Sponsor and to the Canada Vigilance Program (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html)

Date	Drug	Adverse Event	Outcome	Form Tracking Number

First trimester Follow-up (please provide details of embryo/fetal development):

Second trimester Follow-up (please provide details of embryo/fetal development):

Third trimester Follow-up (please provide details of embryo/fetal development):

CHILD INFORMATION:
Neonate

☐ **Live [Normal]** ☐ **Live with congenital abnormality** ☐ **Stillbirth at week**

Please specify any abnormalities: _____

☐ **Full term** ☐ **Premature Number of weeks ____** ☐ **Post-mature Number of weeks ____**

Sex: ☐ **Male** ☐ **Female**

Height: _____cms Weight: _____kgs

Apgar Scores: _____1 min _____5 mins _____10 mins

Head circumference: _____cms

☐ **Breast Fed** ☐ **Bottle Fed**

Neonatal Illness, developmental delay or immaturity? ☐ **Yes, Please specify** _____ ☐ **No**

Corrective treatment Required? ☐ **Yes, Please specify** _____ ☐ **No**

Transfer to ICU or paediatric department?
☐ **Yes, please provide details of location and contact information** _____
☐ **No**
For additional information, (please provide copies of relevant documentation)

ASSESSMENT OF PREGNANCY OUTCOME

SERIOUSNESS CRITERIA

☐ **Non-serious** ☐ **Congenital anomaly/birth defect** ☐ **Death of mother or neonate**

☐ **Involved or prolonged inpatient hospitalization** ☐ **Life-threatening (immediate risk of death)**

☐ **Other significant medical events (may jeopardise the patient or require intervention to prevent one of other criteria).**

☐ **Resulted in persistent or significant disability/incapacity.**

REPORTER INFORMATION

Name: _____ **Title:** _____

Address: _____

City: _____ ***Province:*** _____***Postal Code:*** _____

***Country*:** _____

Institution: _____ **Department:** _____

Phone: _____**Fax:** _____**E- mail:** _____

Healthcare professional: ☐ **Yes** ☐ **No** **If yes, please specify occupation:**

Did patient give consent to follow up with their Healthcare Practitioner for pregnancy outcome and at intervals of 1 week, 6, 12 and 24 months post-delivery?

Patient Name: _____

Healthcare Practitioner:

Name: _____

Address: _____

Phone: _____

Email: _____