**November 25, 2021**

# 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 |
| | | | | | | | |
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**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:** _____