



Teriflunomide Exposure in Pregnancy Form

Date:								
Patient I.D.:								
Country / Province	:							
Report Type:								
Initial								
Follow up								
·								
Exposure during	pregnar	ncy:						
☐ Maternal		•						
☐ Paternal								
Balance I I of	• • •							
Paternal Informa	tion:							
Date of Birth (DD	-MMM	- YYYY)):					
Age: years		•	•					
Ethnicity: Asia	n 🔲 Bla	ck 🔲 (Caucasian \Box H	ispanic 🗀	Other, specify:			
Weight:	gs 🗆 lb	S						
Height: c	m 🗌 in							
Rhesus Factor:								
Medical History	1	T	T	1				
Risk Factor	Yes	No	Risk Factor		Frequency			
				Never	Occasionally	Often	Previously	
							/Quit	
Hepatitis			Substance					
			Abuse					
Hypertension			Alcohol					
Psychiatric			Smoking					
Illness								
Epilepsy								
Diabetes								
HIV								
Other Notable								
Health								
Disorders								
/Conditions:								



Epilepsy Diabetes HIV

Health

Other Notable

Please describe							
Maternal Informa	tion:						
viaterriai illiorilla	itioii.						
Date of Birth (DD	-MMM-Y	YYYY):					
Age: years Ethnicity: Asiar	n Black C	aucasi	ian Hispanic O	ther. spec	ifv:		
Weight: kgs lbs			-	, 5,500	··· , ·		
Height: cm in		_					
Rhesus Factor:	_						
/ledical History							
Risk Factor	Yes	No	Risk Factor		Frequ	ency	
				Never	Occasionally	Often	Previously /Quit
Hepatitis			Substance				
Hamanka este e			Abuse				
Hypertension Psychiatric			Alcohol Smoking	1			
Illness			Jillokilig				



Disorders									
/Conditions	<u> </u>								_
Immunizations:									
Immunization		Yes, Date (D	D-MMM-Y	YYY):	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 Me	netrus	l Doric	74 (TMD) (DD V	48484 VVVV	/\.				
First Day Of Last Ivie	iistiua	renc	Ju (LIVIP) (DD-IV	/IIVIIVI-T T T I	·				
Estimated Delivery Date (DD-MMM-YYYY): Specify method of calculation:									
LMP Ultrasound Date (DD-MMM-YYYY): Other, please specify:									
Did you become pre	egnant	while	on teriflunomi	ide? Ye	s No				
If you got pregnant	while	on ter	iflunomide, wa	as accelera	ted elimi	nation	used?	Yes No	
Teriflunomide Dosage at conception:									
Gestational Age at I	Last Do	se:							
Duration of Treatm	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								

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November 25, 2021



If accelerated elimination was not used, did you become pregnant w discontinuation? Yes No	ithin 2 years of teriflunomide
PATIENT'S MEDICAL HISTORY (include information on familial disorderisk factors or conditions that may affect the outcome of the pregnature other substance consumption, hypertension, eclampsia, diabetes in during pregnancy, environmental or occupational exposure that may	ncy e.g. alcohol, smoking, cluding gestational, infections
PREVIOUS OBSTETRIC HISTORY - provide details on all previous pregincluding abortion or stillbirth:	
Gestation Weeks at Delivery: Outcome of the pregnancy including any previous maternal complic neonatal abnormalities and type:	
Family History: Is there any history of congenital abnormalities, children dying your abnormalities, developmental delays or hereditary diseases in pater 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 me supplements taken prior to or during pregnancy	dications, and dietary
Treatment Dates	Week of pregnancy
Drug Name Daily Dose Route Start Stop (DD-MMM-YYYY): Inc.	Start Stop
Were administered drugs discontinued due to pregnancy? Yes If yes, which drugs?] No

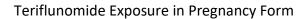
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PRENATAL TESTING: Have any specific tests, e.g. amnio					
sampling, fetal stress test, genetic Yes No Unknown	screening or other be	en performed during the pre	gnancy so far?		
If yes, please specify test date and	results:				
Test	Date: (DD-MMM-YYYY)	Results			
PREGNANCY OUTCOME					
Pregnancy Ongoing: Yes No					
If yes, Gestational age: (weeks) Number of embryos / foetus(es): _					
Last ultrasound scan date (DD-MM Normal Abnormal, please spe			-		
Delivery Date: (DD-MMM-YYYY): _		-			
□Vaginal □ Forceps/ventouse	Caesarean section				
Status of amniotic fluid: \square Clear	☐ Not clear				
Placenta: Normal Abnor	mal				
Medications provided during delivery: yes, please specify No					
Delivery duration:					
Maternal complications or problems related to birth:					
Abortion Date:					
Therapeutic Elective Specify reason and any about		·			

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Unspecified:								
At week								
Complication:								
_								
		():						
☐ Neonate die	□ Neonate died (DD-MMM-YYYY):							
MATERNAL PREGN	ANCY ASSOCIATE	D EVENTS:						
If the mother expe	rienced an advers	e drug reaction during	g pregnancy, pleas	se complete a data				
	•	sted to the Sponsor ar		_				
(https://www.cana canada/adverse-re		canada/services/drug	s-health-products	s/medeffect-				
canada/adverse-re	action-reporting.r	icinij						
Date	Drug	Adverse Event	Outcome	Form Tracking				
				Number				
First trimester Follo	ow-up (please pro	vide details of embry	o/fetal developme	ent):				
Second trimester Follow-up (please provide details of embryo/fetal development):								
Third trimester Fol	low-up (please pro	ovide details of embry	o/fetal developm	nent):				
CHILD INFORMATIO	DN:							
Neonate								
Disco (Normal)	7	nital abnormality \Box S	Satillatinala an anna ala					
Live [Normal]	□ Live with conger	nital abnormality L	otilibirth at week					
Please specify any a	abnormalities:							
Full term Premature Number of weeks Post-mature Number of weeks								
Sex: Male	Fomala							
Jex. Liviale	remale							
Height:	cms Weigh	t:	kgs					
Apgar Scores:	1 min	5 mins	10 mins					
Head circumference	e:	cms						

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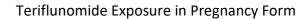
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☐ Breast Fed ☐ Bottle Fed						
Neonatal Illness, developmental delay or immaturity? Yes, Please specify No						
Corrective treatment Required?	Yes, Please specify No					
Transfer to ICU or paediatric department? Yes, please provide details of location and contact information No For additional information, (please provide copies of relevant documentation)						
ASSESSMENT OF PREGNANCY OU	ТСОМЕ					
SERIOUSNESS CRITERIA						
☐ Non-serious ☐ Congenital	anomaly/birth defect Death of mother or neonate					
☐Involved or prolonged inpatien	t 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 signif	icant disability/incapacity.					
REPORTER INFORMATION						
Name:	Title:					
Address:						
City: Pro	vince: Postal Code:					
Country:						
Institution:	Department:					
Phone: Fax:	E- mail:					
Healthcare professional: Yes	No If yes, please specify occupation:					
Did natient give consent to follow u						
intervals of 1 week, 6, 12 and 24 m	up with their Healthcare Practitioner for pregnancy outcome and at onths post-delivery?					

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Healthcare Practitioner:	
Name:	-
Address:	
Phone:	_
Email:	_