



## **Teriflunomide Exposure in Pregnancy Form**

Date:								
Patient I.D.:		_						
Country / Province	:							
Report Type:								
Initial								
Follow up								
·								
Exposure during	oregnar	ncy:						
☐ Maternal								
☐ Paternal								
Paternal Informa	tion:							
Date of Birth (DD	-MMM	-YYYY)	):					
Age:years	□	. —		–	la			
Ethnicity: Asia			Caucasian LIH	ispanic	Other, specify:			
Weight:k		)S						
Height: C								
Rhesus Factor:								
Medical History								
Risk Factor	Yes	No	Risk Factor	Frequency				
				Name		,	Dun da vala	
				Never	Occasionally	Often	Previously /Quit	
Hepatitis			Substance				/Quit	
пераппз			Abuse					
Hypertension			Alcohol					
Psychiatric			Smoking					
Illness								
Epilepsy								
Diabetes								
HIV								
Other Notable								
Health								
Disorders								
/Conditions:								



Epilepsy Diabetes HIV

Health

**Other Notable** 

Please describe							
/laternal Informa	ation:						
Date of Birth (DD Age: years	-MMM-\	YYYY):					
Ethnicity: Asiai			-	ther, spec	ify:		
Weight: kgs lbs _ Height: cm in							
Rhesus Factor:		_					
/ledical History Risk Factor	Yes	No	Risk Factor		Frequ	encv	
Misk i actor	163	140	וווא רמננטו	Never			Droviousla
				Never	Occasionally	Often	Previously /Quit
Hepatitis			Substance				, , , , ,
		<u> </u>	Abuse				
Hypertension			Alcohol				
Psychiatric Illness			Smoking				



Disorders									
/Conditions									
Immunizations:									_
Immunization			Yes, Date (D	D_NANANA_V	vvv\.	No			
Rubella			res, Date (D	D-IVIIVIIVI- I	111).	NO			
Toxoplasmosis									
CMV	•								
Civit									
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 conf	tracep	tion	∟ Con	traceptive	injection				
History of normal or abnormal menstrual cycles History of infertility Yes No									
First Day of Last Menstrual Period (LMP) (DD-MMM-YYYY):									
Estimated Delivery Specify method of c	-								
<ul><li>LMP</li><li>Ultrasound Date (DD-MMM-YYYY):</li><li>Other, please specify:</li></ul>									
Did you become pre	gnant	while	on teriflunomi	de? Yes	No				
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 Treatmo	Duration of Treatment with Product while Pregnant:								
Did you become pre	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 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 OBS		-		•			
including abor	tion or stillbirt	h:					
Gestation Wee	eks at Delivery	•					
Outcome of th							fetal /
neonatal abno	rmalities and t	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							
			Treatment Dates Week of pregna			regnancy	
Drug Name	Daily Dose	Route	Start (DD-MMM- YYYY):	Stop (DD-MMM- YYYY):	Indication	Start	Stop
Were administered drugs discontinued due to pregnancy?  Yes  No If yes, which drugs?							

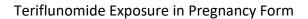
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PRENATAL TESTING:						
Have any specific tests, e.g. amnio						
sampling, fetal stress test, genetic screening or other been performed during the pregnancy so far?						
Yes No Unknown						
If yes, please specify test date and	results:					
Test	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						

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Unspecified:							
At week							
Complication:							
Mother died (DD-MMM-YYYY):  Neonate died (DD-MMM-YYYY):							
_	MATERNAL PREGNANCY ASSOCIATED EVENTS:						
· ·		se drug reaction during ested to the Sponsor an		-			
(https://www.can		n-canada/services/drug	s-health-product	s/medeffect-			
	eaction-reporting.	.numj					
Date	Drug	Adverse Event	Outcome	Form Tracking Number			
First trimester Foll	ow-up (please pr	ovide details of embryo	o/fetal developm	ent):			
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 Weig	ht:	kgs				
Apgar Scores:	1 min	5 mins	10 mins				
Head circumference: cms							

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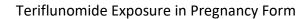
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☐ Breast Fed ☐ Bottle Fed				
Neonatal Illness, developmental delay or immaturity?   Yes, Please specify  No				
Corrective treatment Required?  Yes, Please specify  No				
Transfer to ICU or paediatric department?  Yes, please provide details of location and contact information  No				
For additional information, (please provide copies of relevant documentation)				
ASSESSMENT OF PREGNANCY 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: 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:				

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