

Healthcare Professional Pregnancy Exposure Form

This questionnaire is intended to follow-up on all pregnancy outcomes and born infants up to one (1) year of age for your patient and/or partner of patient.

HEALTHCARE PROFESSIONAL PREGNANCY EXPOSURE FORM	
MINT CONTACT INFORMATION: Telephone: +1 877-398-9696 Fax: +1 866-514-8446 Email: drugsafety@mintpharmaceuticals.com Website: www.mintpharma.com	FOR MINT USE ONLY: Reference case no: Mint Received Date: _____ (YYYY-MM-DD)
I. Reporter Information	
1. Reporter Name	
2. Reporter Qualification ☐ Physician ☐ Pharmacist ☐ Other health professional: _____	
3. Contact Information Email: _____ Phone: _____ Address: _____	
4. Type of Report ☐ Initial: _____ (YYYY-MM-DD) ☐ Follow-up: ☐ First trimester: _____ (YYYY-MM-DD) ☐ Second trimester: _____ (YYYY-MM-DD) ☐ Third trimester: _____ (YYYY-MM-DD) ☐ Infant follow-up: _____ (YYYY-MM-DD)	
II. Patient Consent Consent Obtained: ☐ Yes ☐ No	
III. Maternal/Paternal Medical History	
1. Who was exposed: ☐ Mother and/or ☐ Father (via semen)	
2. Initials	

3. Age 4. Weight 5. Height 6. Rhesus factor: a) Father _____ b) Mother _____																																													
7. Pregnancy History - Number of previous pregnancies: - Number of live births: - Contraceptive methods used:																																													
8. Relevant Medical History/Risk Factors (please indicate where applicable) <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 40%;">Product Name:</th> <th style="width: 30%;">Father</th> <th style="width: 30%;">Mother</th> </tr> </thead> <tbody> <tr><td>Smoking history</td><td></td><td></td></tr> <tr><td>Alcohol history</td><td></td><td></td></tr> <tr><td>Substance abuse</td><td></td><td></td></tr> <tr><td>Occupational/environmental exposure to teratogenic substance</td><td></td><td></td></tr> <tr><td>Hypertension</td><td></td><td></td></tr> <tr><td>Diabetes</td><td></td><td></td></tr> <tr><td>Thyroid disorder</td><td></td><td></td></tr> <tr><td>Asthma</td><td></td><td></td></tr> <tr><td>Heart disease</td><td></td><td></td></tr> <tr><td>Epilepsy</td><td></td><td></td></tr> <tr><td>Psychiatric illness</td><td></td><td></td></tr> <tr><td>HIV</td><td></td><td></td></tr> <tr><td>Hepatitis</td><td></td><td></td></tr> <tr><td>Other notable health disorders/conditions</td><td></td><td></td></tr> </tbody> </table>	Product Name:	Father	Mother	Smoking history			Alcohol history			Substance abuse			Occupational/environmental exposure to teratogenic substance			Hypertension			Diabetes			Thyroid disorder			Asthma			Heart disease			Epilepsy			Psychiatric illness			HIV			Hepatitis			Other notable health disorders/conditions		
Product Name:	Father	Mother																																											
Smoking history																																													
Alcohol history																																													
Substance abuse																																													
Occupational/environmental exposure to teratogenic substance																																													
Hypertension																																													
Diabetes																																													
Thyroid disorder																																													
Asthma																																													
Heart disease																																													
Epilepsy																																													
Psychiatric illness																																													
HIV																																													
Hepatitis																																													
Other notable health disorders/conditions																																													

IV. Exposure to MINT-APREMILAST during Pregnancy

<i>Pregnancy Test</i>	<i>Results</i>	<i>REFERENCE RANGE</i>	<i>DATE</i>
Urine Qualitative			
Serum quantitative			

Pregnancy History (please specify dates where possible)

No. of previous pregnancies:	No. of Full term deliveries:	No. of Pre-term births:
Date of last pregnancy:		
No. of fetal deaths:	No. of living children:	No. of abortions: (Elective/Spontaneous)
Type of delivery (Vaginal):	Type of delivery (C-section):	Other., (eg: <i>history of infertility</i>) :
Did birth defect occur in any previous pregnancy? No Yes Unknown If Yes, specify		

Menstrual History:

Normal cycles (DD-MMM-YYYY to DD-MMM-YYYY):

Abnormal cycles (DD-MMM-YYYY to DD-MMM-YYYY):

1. LMP:
2. Types of contraception:
3. Contraception dates (with start/stop dates):

4. Maternal Immunization History:

Immunization		Date
Toxoplasmosis		
Cytomegalovirus		
CMV		
Rubella		
Others (please specify)		

5. Relevant Medical History/Risk Factors

6. Apremilast therapy information:

Dose _____; Route _____; Therapy dates _____;

7. Apremilast/Concomitant medications/treatments/supplements:

Product Name:	Dosage Regimen	Start Date: (YYYY-MM-DD)	Stop Date/Ongoing: (YYYY-MM-DD)	Indication of Use:

8. Gestation age at birth:

9. Duration of treatment:

Pregnancy Information

1. Estimated delivery date: _____

Prenatal tests conducted on mother/foetus

<i>Test</i>	<i>Result</i>	<i>DATE</i>
Genetic testing for any chromosomal abnormalities		
Prenatal cell-free DNA screening		
Maternal serum screening		
Non-invasive prenatal testing		
Ultrasound		
Amniocentesis		
Percutaneous umbilical cord blood sampling		
Chorionic villi sampling		
Maternal Serum AFP		
Other (please specify)		

V. Pregnancy outcome1. Trimester Follow-up: ☐ First ☐ Second ☐ Third

Tests performed	Results	Date	Status of the embryo/fetal development:	Trimester

Maternal Complications and Adverse Event(s) During Pregnancy

Event(s) and description	Serious (Yes or No)	Serious criteria ¹	Start date (DD-MMM-YYYY)	Stop date (DD-MMM-YYYY)	Causal relationship to the therapy	Trimester	Was it reported to Canada Vigilance Program (Please provide AE tracking number)

¹ Serious Criteria: **1)** death, **2)** life-threatening, **3)** required inpatient hospitalization or prolongation of existing hospitalization, **4)** a persistent or significant disability/incapacity, **5)** a congenital anomaly/birth defect, **6)** medically significant

2. Actual delivery date: _____

Overall pregnancy outcome (*Choose all that apply*)

☐ Ongoing

☐ Ectopic
Pregnancy

☐ Spontaneous
Abortion

☐ Full-term

☐ Livebirth:

☐ Stillbirth

☐ Elective
Termination

☐ Therapeutic
Abortion

☐ Premature live
birth

☐ Unknown

(if applicable)

☐ C-Section

☐ Induced

3. Gestational age at outcome:

4. Date if applicable (YYYY-MM-DD):

5. Delivery Type ☐ Vaginal ☐ Forceps ☐ Ventouse ☐ Caesarean

6. Status of the amniotic fluid ☐ clear ☐ not clear

7. Status of Placenta ☐ Normal ☐ Abnormal

VI. Infant/Neonate details (At birth)

1. Birth weight: _____

2. Gestational age at birth:

3. Sex:

4. Head circumference:

5. APGAR Scores:

at 1 min- _____

at 5 min- _____

at 10 min- _____

6. Foetal outcome

☐ Normal

☐ Abnormal (if birth defects/congenital abnormalities and other events experienced by the foetus/baby)

☐ Unknown

VI. Infant follow-up

☐ At 6 months ☐ At 1 year

Infant status:

☐ Living ☐ Deceased

Weight:

Height:

Sex:

Head circumference:

Anomalies Diagnosed:

Developmental Assessment:

Relevant Medical Information:

Infant Medical History: *(Hospitalization, health concerns, evidence that the infant is immunocompromised, surgeries, or history of infection):*

Infant Diet *(e.g. breastfed or weaned, feedings in addition to breast milk, or description of diet if eating solids)*

Paediatrician contact information and date:

Additional Information or Comments:

Infant Drug Exposure (Please provide a list of medications and start/stop dates of those given to the infant directly, or medications taken by the mother with potential for indirect exposure to the infant via breastmilk):

Product Name:	Route (EX.: Given to Infant, via mother, breastmilk, etc)	Start Date: (YYYY-MM-DD)	Stop Date/Ongoing: (YYYY-MM-DD)	Indication of Use:

Relevant laboratory Tests/ Procedures for Baby:

Test Name	Result	DATE

Infant adverse events: Please report any Infant adverse events, hospitalization, or any special treatment:

Infant Milestones

Infant Milestones	Age	Date
Infant rolled over		
Reached for objects		
Sat up without support		
Turned to locate a voice		
Said first word		
Stood alone		
Others (please specify)		

Reporter Signature:	Date (YYYY-MM-DD):
<i>FOR MINT USE ONLY:</i> Signature: Print Name:	Date (YYYY-MM-DD):