

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	
<p>MINT CONTACT INFORMATION:</p> <p>Telephone: +1 877-398-9696</p> <p>Fax: +1 866-514-8446</p> <p>Email: drugsafety@mintpharmaceuticals.com</p> <p>Website: www.mintpharmaceuticals.com</p>	<p>FOR MINT USE ONLY:</p> <p>Reference case no:</p> <p>Mint Received Date: _____ (YYYY-MM-DD)</p>
I. Reporter Information	
1. Reporter Name	
2. Reporter Qualification	
<input type="checkbox"/> Physician <input type="checkbox"/> Pharmacist <input type="checkbox"/> Other health professional: _____	
3. Contact Information	
Email: _____	
Phone: _____	
Address: _____	
4. Type of Report	
<input type="checkbox"/> Initial: _____ (YYYY-MM-DD) <input type="checkbox"/> Follow-up: <ul style="list-style-type: none"> <input type="checkbox"/> First trimester: _____ (YYYY-MM-DD) <input type="checkbox"/> Second trimester: _____ (YYYY-MM-DD) <input type="checkbox"/> Third trimester: _____ (YYYY-MM-DD) <input type="checkbox"/> Infant follow-up: _____ (YYYY-MM-DD) 	
II. Maternal/Paternal Medical History	
1. Who was exposed: <input type="checkbox"/> Mother and/or <input type="checkbox"/> Father (via semen)	
2. Initials	

3. Age		
4. Weight		
5. Height		
6. Rhesus factor: a) Father _____ b) Mother _____		
7. Pregnancy History		
<ul style="list-style-type: none"> • Number of previous pregnancies: • Number of live births: • Contraceptive methods used: 		
8. Relevant Medical History/Risk Factors (please indicate where applicable)		
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		

III. 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: _____

2. Genetic testing for any chromosomal abnormalities:

<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		
Other (please specify)		

3. Prenatal tests conducted on mother/foetus:

<i>Prenatal Tests</i>	<i>Result</i>	<i>DATE</i>
Ultrasound		
Ultrasound		
Ultrasound		
Amniocentesis		
Maternal Serum AFP		

IV. Pregnancy outcome

1. 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*)

- | | | | |
|---|--|---|---|
| <input type="checkbox"/> Ongoing | <input type="checkbox"/> Ectopic Pregnancy | <input type="checkbox"/> Spontaneous Abortion | <input type="checkbox"/> Full-term |
| <input type="checkbox"/> Livebirth: | <input type="checkbox"/> Stillbirth | <input type="checkbox"/> Elective Termination | <input type="checkbox"/> Therapeutic Abortion |
| <input type="checkbox"/> Premature live birth | | | <input type="checkbox"/> 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

V. Infant/Neonate details (At birth)

1. Birth weight: _____
2. Sex:
3. Head circumference:
4. APGAR Scores:
 - at 1 min- _____
 - at 5 min- _____
 - at 10 min- _____

5. 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):
FOR MINT USE ONLY: Signature: Print Name:	Date (YYYY-MM-DD):