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)

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

Pregnancy Test	*Results*	*REFERENCE RANGE*	*DATE*
Urine Qualitative			
Serum quantitative			

Pregnancy History (*please specify dates where possible)*

No. of previous pregnancies: Date of last pregnancy:	No. of Full term deliveries:	No. of Pre-term births:
No. of fetal deaths:	No. of living children:	No. of abortions: (Elective/Spontaneous)
Type of delivery (Vaginal):	Type of delivery (C-section):	Other:, (eg: *history of infertility*) :
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

Test	*Result*	*DATE*
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 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*)

☐ Ongoing ☐ Ectopic Pregnancy ☐ Spontaneous Abortion ☐ Full-term

☐ Livebirth: ☐ Stillbirth ☐ Elective Termination ☐ Therapeutic Abortion

☐ Unknown

☐ Premature live birth

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