



PROMACTA (eltrombopag) PREGNANCY OUTCOME FORM

GSK Reference No.:

Section 1 - Maternal data

Age: _____ years Weight: <input type="checkbox"/> Kg <input type="checkbox"/> lb Height: <input type="checkbox"/> cm <input type="checkbox"/> inches	Date of birth: _____ Day Month Year Promacta CARES Identification: _____	Ethnic origin: <input type="checkbox"/> Black <input type="checkbox"/> Hispanic <input type="checkbox"/> White <input type="checkbox"/> Asian <input type="checkbox"/> Oriental <input type="checkbox"/> Other (specify): _____	Date of last menstrual period: _____ Day Month Year Final estimated date of delivery by ultrasound: _____ Day Month Year No. of fetuses (e.g. twins): _____
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Was this a normal conception (includes fertility drugs)? Yes No
 In-vitro fertilization? Yes No

Section 2 - Maternal pre-natal medication/vaccine exposure

Please list all medications (prescription and over-the-counter) and vaccines, taken by the mother within 3 months prior to or during pregnancy. Please list GSK medication(s)/vaccine(s) first.
 Describe each course of therapy or change in route or dose of therapy.

Drug / Vaccine / OTC Name (Generic or Trade Name)	Batch/Lot No. & Expiry Date	Formulation (e.g. tablet, injection) & Route (e.g. oral, IV)	Total Daily Dose (e.g. 20mg daily)	Date Course Began (dd/mm/yy)	Date Course Ended (dd/mm/yy)	Gestation Weeks of Exposure (e.g. wk 28 - wk 32)	Indication for Treatment
Promacta (eltrombopag)							

Note: Please indicate with an asterix * the medication(s)/vaccine(s) that were considered related to any adverse events reported in section 3 (if applicable)

Section 3 – Maternal adverse event reporting

If the mother experienced an adverse event, please complete the following:

	Yes	No		Yes	No
<input type="checkbox"/> Immune system development	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Bone marrow reticulin formation	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Platelet number and function	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Thrombotic events	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Neoplasm formation	<input type="checkbox"/>	<input type="checkbox"/>			

If yes, please provide specific information in the following section.

If the **mother** experienced any other adverse event, please also include this information in the following section.

Adverse Event(s)	Onset Date (dd/mm/yy)	End Date (dd/mm/yy)	Outcome (please select one)	Relationship to Promacta	Relationship to other Medications
			<input type="checkbox"/> Fatal <input type="checkbox"/> Unresolved <input type="checkbox"/> Resolved <input type="checkbox"/> Worse <input type="checkbox"/> Improved <input type="checkbox"/> Sequelae <input type="checkbox"/> Unknown	<input type="checkbox"/> Related <input type="checkbox"/> Unrelated <input type="checkbox"/> Possible <input type="checkbox"/> Unknown	<input type="checkbox"/> Related <input type="checkbox"/> Unknown <input type="checkbox"/> Unrelated <input type="checkbox"/> Possible Please list medication(s)
			<input type="checkbox"/> Fatal <input type="checkbox"/> Unresolved <input type="checkbox"/> Resolved <input type="checkbox"/> Worse <input type="checkbox"/> Improved <input type="checkbox"/> Sequelae <input type="checkbox"/> Unknown	<input type="checkbox"/> Related <input type="checkbox"/> Unrelated <input type="checkbox"/> Possible <input type="checkbox"/> Unknown	<input type="checkbox"/> Related <input type="checkbox"/> Unknown <input type="checkbox"/> Unrelated <input type="checkbox"/> Possible Please list medication(s)
			<input type="checkbox"/> Fatal <input type="checkbox"/> Unresolved <input type="checkbox"/> Resolved <input type="checkbox"/> Worse <input type="checkbox"/> Improved <input type="checkbox"/> Sequelae <input type="checkbox"/> Unknown	<input type="checkbox"/> Related <input type="checkbox"/> Unrelated <input type="checkbox"/> Possible <input type="checkbox"/> Unknown	<input type="checkbox"/> Related <input type="checkbox"/> Unknown <input type="checkbox"/> Unrelated <input type="checkbox"/> Possible Please list medication(s)
			<input type="checkbox"/> Fatal <input type="checkbox"/> Unresolved <input type="checkbox"/> Resolved <input type="checkbox"/> Worse <input type="checkbox"/> Improved <input type="checkbox"/> Sequelae <input type="checkbox"/> Unknown	<input type="checkbox"/> Related <input type="checkbox"/> Unrelated <input type="checkbox"/> Possible <input type="checkbox"/> Unknown	<input type="checkbox"/> Related <input type="checkbox"/> Unknown <input type="checkbox"/> Unrelated <input type="checkbox"/> Possible Please list medication(s)

Do you consider the maternal adverse event(s) to be **SERIOUS**? Yes No

If yes, please indicate why the event is considered to be serious (tick all that apply):

Life threatening? Severely or permanently disabling? Required or prolonged hospitalization?

Congenital anomaly? Jeopardized patient or required intervention? Patient died?

If patient died, what was the cause of death? _____ Date of death (dd/mm/yy)? _____

Section 4 – Pregnancy outcome

If multiple births please duplicate Section 4 as necessary to permit separate reporting for each infant

Multiple infants: Number (e.g. twins): _____ Birth order (1st, 2nd, 3rd etc): _____

Date pregnancy ended:

Day Month Year

Gestational age at birth/
miscarriage/termination:

_____ weeks

Outcome	Birth defect noted?	
<input type="checkbox"/> Live infant	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<input type="checkbox"/> Abortion spontaneous/miscarriage (< 20 weeks)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<input type="checkbox"/> Abortion induced, medical reason	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<input type="checkbox"/> Abortion induced, non medical reason	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<input type="checkbox"/> Stillbirth/late foetal death (> 20 weeks)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<input type="checkbox"/> Ectopic pregnancy (< 20 weeks)	N/A	N/A
<input type="checkbox"/> Molar pregnancy (< 20 weeks)	N/A	N/A

Method of delivery: Normal vaginal Forceps Cesarean section Other: _____

Gender: Male Female Full-term (37-42 weeks) Pre-term (< 37 weeks) Post-term (> 42 weeks)

Birth weight: _____ g/lb Length: _____ cm/inches Head circumference: _____ cm/inches

APGAR score (0-10) at 1 minute & 5 minutes: ____ / ____ Significant functional impairment

Small for gestation age Large for gestation age Intrauterine growth restriction

Section 5 – Neonate/Infant adverse event reporting

If the neonate/infant experienced an adverse event, please complete the following:

	Yes	No		Yes	No
<input type="checkbox"/> Immune system development	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Bone marrow reticulin formation	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Platelet number and function	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Thrombotic events	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Neoplasm formation	<input type="checkbox"/>	<input type="checkbox"/>			

If yes, please provide specific information in the following section.

If the **neonate/infant** experienced any other adverse event, please also include this information in the following section.

Adverse Event(s)	Onset Date (dd/mm/yy)	End Date (dd/mm/yy)	Outcome (please select one)	Relationship to Promacta	Relationship to other Medications
			<input type="checkbox"/> Fatal <input type="checkbox"/> Unresolved <input type="checkbox"/> Resolved <input type="checkbox"/> Worse <input type="checkbox"/> Improved <input type="checkbox"/> Sequelae <input type="checkbox"/> Unknown	<input type="checkbox"/> Related <input type="checkbox"/> Unrelated <input type="checkbox"/> Possible <input type="checkbox"/> Unknown	<input type="checkbox"/> Related <input type="checkbox"/> Unknown <input type="checkbox"/> Unrelated <input type="checkbox"/> Possible Please list medication(s)
			<input type="checkbox"/> Fatal <input type="checkbox"/> Unresolved <input type="checkbox"/> Resolved <input type="checkbox"/> Worse <input type="checkbox"/> Improved <input type="checkbox"/> Sequelae <input type="checkbox"/> Unknown	<input type="checkbox"/> Related <input type="checkbox"/> Unrelated <input type="checkbox"/> Possible <input type="checkbox"/> Unknown	<input type="checkbox"/> Related <input type="checkbox"/> Unknown <input type="checkbox"/> Unrelated <input type="checkbox"/> Possible Please list medication(s)
			<input type="checkbox"/> Fatal <input type="checkbox"/> Unresolved <input type="checkbox"/> Resolved <input type="checkbox"/> Worse <input type="checkbox"/> Improved <input type="checkbox"/> Sequelae <input type="checkbox"/> Unknown	<input type="checkbox"/> Related <input type="checkbox"/> Unrelated <input type="checkbox"/> Possible <input type="checkbox"/> Unknown	<input type="checkbox"/> Related <input type="checkbox"/> Unknown <input type="checkbox"/> Unrelated <input type="checkbox"/> Possible Please list medication(s)
			<input type="checkbox"/> Fatal <input type="checkbox"/> Unresolved <input type="checkbox"/> Resolved <input type="checkbox"/> Worse <input type="checkbox"/> Improved <input type="checkbox"/> Sequelae <input type="checkbox"/> Unknown	<input type="checkbox"/> Related <input type="checkbox"/> Unrelated <input type="checkbox"/> Possible <input type="checkbox"/> Unknown	<input type="checkbox"/> Related <input type="checkbox"/> Unknown <input type="checkbox"/> Unrelated <input type="checkbox"/> Possible Please list medication(s)

Do you consider the neonate/infant adverse event(s) to be **SERIOUS**? Yes No

If yes, please indicate why the event is considered to be serious (tick all that apply):

Life threatening? Severely or permanently disabling? Required or prolonged hospitalization?

Congenital anomaly? Jeopardized infant or required intervention? Infant died?

If the infant died, what was the cause of death? _____ Date of death (dd/mm/yy)? _____

If any birth defects (structural/chromosomal disorder) were noted, please describe (please include severity of malformation, surgery planned, conclusions of genetic counseling etc):

Was the defect evident from a prenatal or postnatal test (e.g. amniocentesis, ultrasound, MS/AFP)?

Yes No

(If yes please provide details in the section below)

Section 6 – Laboratory and Procedures

Relevant laboratory tests & procedures. (In case of an abnormal evolution or outcome, please send a copy of all relevant laboratory tests and procedures e.g. autopsy results on fetus/neonate):

Test Name	Test Date (dd/mm/yy)	Test Result	Test Units	Low Norm	High Norm

Section 7 - Maternal pre-natal medication/vaccine exposure

Please list any medications the neonate/infant received following delivery:

Please indicate with an asterix * the medication(s)/vaccine(s) that were considered related to any adverse events reported in section 3 or 5 (if applicable)

Drug Name (Generic or Trade Name)	Batch/Lot No. & Expiry Date	Formulation & Route (e.g. syrup, oral)	Total Daily Dose (e.g. 20mg daily)	Date Course Began (dd/mm/yy)	Date Course Ended (dd/mm/yy)	Indication for Treatment

To what do you attribute any problems/defects?

Do you believe they may be drug/vaccine related? Yes No If yes, please specify to which drug/vaccine.

Was the exposure via the mother (transplacental, or via breastfeeding), or direct (to infant following delivery, or to foetus directly in utero)?

Additional details on neonate/infant including any physical examination, resuscitation, ICU admission, reason for termination etc. Describe any immediate postnatal problems/neonatal illnesses (e.g. jaundice, respiratory distress). (Please attach copy of examination report/discharge summary if available):

Section 8 - Maternal relevant medical/family history

Please provide number of previous pregnancies in categories below and any additional details in space for text:

Full-term:	Number and Details:	Pre-Term:	Number and Details:
<input type="checkbox"/> Normal birth	_____	<input type="checkbox"/> Spontaneous abortion	_____
<input type="checkbox"/> Still birth	_____	<input type="checkbox"/> Therapeutic abortion	_____
<input type="checkbox"/> Birth defect	_____	<input type="checkbox"/> Pre-term labour:	_____
<input type="checkbox"/> Outcome unknown	_____	<input type="checkbox"/> Other (specify):	_____

Please describe any additional factors that may have had an impact on the outcome of this pregnancy, including relevant medical or family history, mother's occupation, use of recreational drugs, illnesses during pregnancy etc. Please specify other disorders including familial birth defects/genetic/chromosomal disorders, consanguinity etc.:

Tobacco use: _____ Alcohol intake: _____

Section 9 – Infant Healthcare Provider Contact Information

Name of Infant's Healthcare Provider:

Telephone Number:

Address:

Fax Number:

Email address:

Section 10 - Reporter information

Country of Reporter:

Relationship to patient:

Occupation of Reporter:
(e.g. Physician, Obstetrician, Nurse etc.)

(e.g. Healthcare provider, Spouse, Relative etc.)

Regulatory reporting

Agency Reference No. (if known):

Have you reported this case to a Regulatory Agency? Yes No