

PROMACTA (eltrombopag) PREGNANCY INITIAL NOTIFICATION FORM

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.

ADrug / 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:

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 – Fetal adverse event reporting

If the **fetus** experienced an adverse event, please complete the following:

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)

Section 4 – Fetal adverse event reporting (continued)

Do you consider the fetal 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? Jeopardised patient or required intervention? Patient died?

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

Section 5 – Laboratory and Procedures

Relevant laboratory tests & procedures

In case of an abnormal outcome, please send a copy of all relevant laboratory tests and procedures e.g. autopsy results

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

Section 6 – Additional details

Please include complications during pregnancy, diagnostic results (including prenatal screening tests), any relevant maternal/paternal medical history etc.

Section 7 - Reporter information

Country of Reporter: _____

Occupation of Reporter: _____

(e.g. Physician, Obstetrician, Nurse etc.)

Relationship to patient: _____

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

Regulatory reporting

Have you reported this case to a Regulatory Agency?

Yes No

Agency Reference No. (if known): _____