

PROMACTA (eltrombopag) ONE YEAR FOLLOW UP FORM

Section 1 – Infant 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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Section 2 - Infant medication/vaccine exposure

Please list all medications (prescription and over-the-counter) and vaccines, taken by the **infant (including via breast milk)**. 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)	Indication for Treatment

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)

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 fetus directly in utero)?

Section 3 – Infant adverse event reporting

If the **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 **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 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)? _____

Section 4 – Defect Information

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 post natal test (e.g. amniocentesis, ultrasound, MS/AFP)?

Yes No

(If yes please provide details)

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 on infant):

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

Additional details on 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 6 - Reporter information

Country of Reporter:

Relationship to patient:

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

Occupation of Reporter:

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

Regulatory reporting

Have you reported this case to a Regulatory Agency?

Yes No

Agency Reference No. (if known):