GlaxoSmithKline

GSK Reference No.:

PROMACTA (eltrombopag)
ONE YEAR FOLLOW UP FORM

Section 1 – Infant data

Age: years

Weight: ☐ Kg ☐ lb

Height: ☐ cm ☐ inches

Date of birth:
_____
Day Month Year

Promacta CARES Identification:
_____

Ethnic origin:
☐ Black
☐ Hispanic
☐ White
☐ Asian
☐ Oriental
☐ 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): _____

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 (transplacentary, 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
☐ Immune system development	☐	☐	☐ Bone marrow reticulin formation	☐	☐
☐ Platelet number and function	☐	☐	☐ Thrombotic events	☐	☐
☐ Neoplasm formation	☐	☐			

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**
			☐ Fatal ☐ Unresolved ☐ Resolved ☐ Worse ☐ Improved ☐ Sequelae ☐ Unknown	☐ Related ☐ Unrelated ☐ Possible ☐ Unknown	☐ Related ☐ Unknown ☐ Unrelated ☐ Possible Please list medication(s)
			☐ Fatal ☐ Unresolved ☐ Resolved ☐ Worse ☐ Improved ☐ Sequelae ☐ Unknown	☐ Related ☐ Unrelated ☐ Possible ☐ Unknown	☐ Related ☐ Unknown ☐ Unrelated ☐ Possible Please list medication(s)
			☐ Fatal ☐ Unresolved ☐ Resolved ☐ Worse ☐ Improved ☐ Sequelae ☐ Unknown	☐ Related ☐ Unrelated ☐ Possible ☐ Unknown	☐ Related ☐ Unknown ☐ Unrelated ☐ Possible Please list medication(s)
			☐ Fatal ☐ Unresolved ☐ Resolved ☐ Worse ☐ Improved ☐ Sequelae ☐ Unknown	☐ Related ☐ Unrelated ☐ Possible ☐ Unknown	☐ Related ☐ Unknown ☐ Unrelated ☐ 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):