GlaxoSmithKline

PREGNANCY OUTCOME FORM

GSK Reference No:

GSK Receipt Date:
(dd/mm/yyyy)

Section 1 - Maternal data

Initials:

Age: years

Weight: ☐ Kg ☐ lb

Height: ☐ cm ☐ inches

Date of birth:
_____
Day Month Year

Patient I.D. / medical records number:
_____

Ethnic origin:
☐ Black
☐ Hispanic
☐ White
☐ Asian
☐ Oriental
☐ Other (specify):
_____

Date of last menstrual period:
_____
Day Month Year

Estimated date of delivery:
_____
Day Month Year

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**.

Describe each course of therapy or change in route or dose of therapy.

Note: For cases of paternal exposure (pregnancy in the partner of a male patient receiving medications/vaccines) please describe details of any medications/vaccines and any other relevant information in Section 7 below.

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**

Note: Please indicate with an asterix ***** the medication(s)/vaccine(s) that were considered suspect (if applicable)

Section 3 – Maternal adverse event reporting

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

Adverse Event	Onset Date/ End Date (dd/mm/yy)	Is the AE a result of a suspected transmission of an infectious agent via a medicinal product?	Outcome			Relationship to Product(s)	
		☐ Yes ☐ No	☐ Sequelae ☐ Worse	☐ Sequelae ☐ Worse	☐ Improved ☐ Unknown	☐ Related ☐ Unrelated	☐ Possible ☐ Unknown
		☐ Yes ☐ No	☐ Resolved ☐ Unresolved	☐ Sequelae ☐ Worse	☐ Improved ☐ Unknown	☐ Related ☐ Unrelated	☐ Possible ☐ Unknown
		☐ Yes ☐ No	☐ Resolved ☐ Unresolved	☐ Sequelae ☐ Worse	☐ Improved ☐ Unknown	☐ Related ☐ Unrelated	☐ Possible ☐ Unknown
		☐ Yes ☐ No	☐ Resolved ☐ Unresolved	☐ Sequelae ☐ Worse	☐ Improved ☐ Unknown	☐ Related ☐ Unrelated	☐ Possible ☐ Unknown

Do you consider the 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**

☐ **Jeopardised patient or required intervention** ☐ **Mother died – 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?	
☐ Live infant	☐ Yes	☐No
☐ Abortion spontaneous/miscarriage (< 22 weeks)	☐ Yes	☐No
☐ Abortion induced, medical reason	☐ Yes	☐No
☐ Abortion induced, non medical reason	☐ Yes	☐No
☐ Stillbirth/late foetal death (> 22 weeks)	☐ Yes	☐No
☐ Ectopic pregnancy (< 22 weeks)	N/A	N/A
☐ Molar pregnancy (< 22 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: __ __ / __ __

If the outcome of the pregnancy was normal:

There is no need to complete Sections 5, 6 and 7.

Exception: Paternal exposure to any medications/vaccines - please ensure Section 7 is completed.

Section 5 – Infant/Foetal information

Additional details on foetus/infant including any adverse events, 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):

Do you consider the 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**

☐ **Jeopardised infant or required intervention** ☐ **Infant died: Cause of death**_____ **Date of death (dd/mm/yy):** _____

☐ **Congenital Anomaly**

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

Was the defect evident from a prenatal test (e.g. amniocentesis, ultrasound, MS/AFP)? ☐ Yes ☐ No

(If yes please provide details in investigations section below)

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 foetus/neonate):

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

Please list any medications the neonate received following delivery:

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 (transplacentary, or via breastfeeding), or direct (to infant following delivery, or to foetus directly in utero)?

Section 6 - Maternal relevant medical/family history

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

Full-term:	No. and Details:	**Pre-Term:**	No. and Details:
☐ Normal birth:	_____	☐ Spontaneous abortion:	_____
☐ Still birth:	_____	☐ Therapeutic abortion:	_____
☐ Birth defect:	_____	☐ Pre-term labour:	_____
☐ Outcome unknown:	_____	☐ 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 7 - Paternal relevant medical/family history

Please include age/birth date, occupation, relevant illnesses, familial birth defects/genetic/chromosomal disorders, habitual exposure to alcohol/tobacco, substance abuse and medication use. For cases of paternal exposure to any medications/vaccines, please specify dates of exposure, formulation, route, daily dose received:

Section 8 - Reporter information

Reporters Name:
Address:

Country:
Telephone No.:
Fax No.:

Title:
(e.g. Dr. Professor, Mr., Mrs., Miss, Ms etc.)
Occupation:
(*e.g. Physician, Obstetrician, Nurse etc.)*
Relationship to patient:
(e.g. Healthcare provider, Spouse, Relative etc.)

Reporter's Signature: _____ **Date:** _____

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

Agency Reference No. (if known):