

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)	
			Sequelae Worse	Sequelae Worse	Improved Unknown	Related Unrelated	Possible Unknown
		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Resolved <input type="checkbox"/> Unresolved	<input type="checkbox"/> Sequelae <input type="checkbox"/> Worse	<input type="checkbox"/> Improved <input type="checkbox"/> Unknown	<input type="checkbox"/> Related <input type="checkbox"/> Unrelated	<input type="checkbox"/> Possible <input type="checkbox"/> Unknown
		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Resolved <input type="checkbox"/> Unresolved	<input type="checkbox"/> Sequelae <input type="checkbox"/> Worse	<input type="checkbox"/> Improved <input type="checkbox"/> Unknown	<input type="checkbox"/> Related <input type="checkbox"/> Unrelated	<input type="checkbox"/> Possible <input type="checkbox"/> Unknown
		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Resolved <input type="checkbox"/> Unresolved	<input type="checkbox"/> Sequelae <input type="checkbox"/> Worse	<input type="checkbox"/> Improved <input type="checkbox"/> Unknown	<input type="checkbox"/> Related <input type="checkbox"/> Unrelated	<input type="checkbox"/> Possible <input type="checkbox"/> 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:

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 (< 22 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 (> 22 weeks)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<input type="checkbox"/> Ectopic pregnancy (< 22 weeks)	N/A	N/A
<input type="checkbox"/> 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 (transplacental, 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:
<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 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:	Title:
Address:	<i>(e.g. Dr. Professor, Mr., Mrs., Miss, Ms etc.)</i>
Country:	Occupation:
Telephone No.:	<i>(e.g. Physician, Obstetrician, Nurse etc.)</i>
Fax No.:	Relationship to patient:
	<i>(e.g. Healthcare provider, Spouse, Relative etc.)</i>

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

Have you reported this case to a Regulatory Agency? Yes No Agency Reference No. (if known): _____