End of Pregnancy Form

CONFIDENTIAL

Reserved for Nordic reference : _____	**Please send this form to :** Global Surveillance Patient Safety, 216 Bd St Germain 75007 Paris, France, E-mail: pv@nordicpharma.com Tel : + 33 (0) 1 70 37 28 02 Fax :+ 33 (0) 1 70 37 28 29

Patient Initials: Forename: ___ Surname: ____ Age |__|__|

1. MOTHER INFORMATION

1.1 Obstetrical history:

Gravidity |____| Parity |____|
Pathological pregnancy ☐No ☐Yes
Fœtal / neonatal abnormalities ☐No ☐Yes

1.2 Pregnancy ongoing:

Risks factors: ☐Diabetes ☐Cardiac pathology ☐Allergy
☐ Other……..

Pathology during pregnancy ☐ No ☐ Yes

Date of Last Mensual Period (LMP): ___/___/____ (dd/mm/yyyy)
Estimated date of delivery : ___/___/____ (dd/mm/yyyy)

1.3 Delivery:

☐Vaginal delivery
☐Caesarian, indication: ……..
☐Termination of pregnancy for medical reasons,
Date ___/___/____ (dd/mm/yyyy),
Term |__|__| Weeks post Last Mensual Period (W-LMP)

☐Termination of pregnancy,
Date ___/___/____ (dd/mm/yyyy),
Term |__|__| Weeks post Last Mensual Period (W-LMP)

1.4 Delivery complication? ☐No ☐Yes
specify: ……..

1.5 Drug received during pregnancy? ☐No ☐Yes
(If yes, complete the table below)

Product	Route of administration	Posology	Start date	Stop date	Therapeutic Indications
1. **Batch number**					
2. **Batch number**					
3. **Batch number**					
4. **Batch number**					

End of Pregnancy Form

2. TESTS PERFORMED DURING PREGNANCY

2.1 Tests during pregnancy were performed?

☐No *(if no, go to the section 3)*

☐Yes

☐Ultrasound exam ___/___/___ (dd/mm/yyyy),Term|__|__|W-LMP

☐Ultrasound exam ___/___/___ (dd/mm/yyyy),Term|__|__| W-LMP

☐ Ultrasound exam ___/___/___ (dd/mm/yyyy),Term|__|__| W-LMP

☐Amniocentesis ___/___/___ (dd/mm/yyyy),Term|__|__| W-LMP

☐Serology test ___/___/___ (dd/mm/yyyy),Term|__|__| W-LMP

☐Other ……..

___/___/___ (dd/mm/yyyy),Term |__|__| W-LMP

☐ Unknown *(go to the section 3)*

2.2 Structural malformation diagnosed with tests performed during pregnancy:

☐No *(If no, go to the section 3)* ☐Yes, specify:

……

……

……

Test(s) which allowed detection of the malformation (✓) :

☐Ultrasound exam ___/___/____ (dd/mm/yyyy),Term|__|__| W-LMP

☐Amniocentesis ___/___/____ (dd/mm/yyyy),Term|__|__| W-LMP

☐Serology test ___/___/____ (dd/mm/yyyy),Term|__|__| W-LMP

☐Other……

___/___/____ (dd/mm/yyyy),Term|__|__| W-LMP

☐Unknown *(go to the section 3)*

3. NEONATAL

3.1 Date of birth : ___/___/____ (dd/mm/yyyy)

3.2 Pregnancy term at birth : |__|__| W-post-LMP

3.3 Sex : ☐Female ☐Male

3.4 Weight at birth : _____ Kg

3.5 Height at birth : _____ cm

3.6 Head circumference at birth: _____ cm

3.7 Abnormalities detected at birth: ☐No ☐Yes *(If yes, specify)*

……

……..……

3.8 Neonatal pathology: ☐No ☐Yes (*If yes, specify)*

……

……

3.9 Maternal breast feeding: ☐No ☐Yes (*If yes, specify)*

……

……

4. ONE YEAR-OLD OUTCOME:

Abnormalities detected one year after delivery:☐No☐Yes *(If yes, specify)*

……

……

……

Specify causal relationship with drug intake during pregnancy

☐ No ☐Yes (*If yes, specify which product*)

……

……

……

5. ADVERSE EVENT

☐No ☐Yes *(if yes, go to the section 4)*

5.1 Adverse event experienced by : ☐neonate ☐mother

5.2 Onset date (neonate) : ___/___/____ (dd/mm/yyyy)

Onset date (mother) : ___/___/____ (dd/mm/yyyy)

5.3 Duration: ……..

End date: ___/___/____ (dd/mm/yyyy)

5.4 Is a product suspected (causality)? ☐No ☐Yes, *If yes, specify*

……

……

5.5 Seriousness (✓):

☐ Death, date: ___/___/____ (dd/mm/yyyy)

☐ Life threatening

☐ Congenital anomaly/Birth defect

☐ Involved/Prolonged patient hospitalization

☐ Involved persistent or significant disability/incapacity

☐ Important medical event

5.6 Outcome (✓):

☐ Recovered ☐ Recovered with sequelae

☐ Death due to the adverse event

☐ Death might be due to the adverse event

☐ Death not due to the adverse event

☐ Not recovered ☐ Unknown

5.7 Description of the adverse event (please, attach additional test of the mother/child):

……

……

End of Pregnancy Form

6. PATERNAL DRUG EXPOSURE DURING THE MONTH BEFORE CONCEPTION					
Product	**Route**	**Posology**	**Start**	**Stop**	**Therapeutic Indications**
1.					
2.					
3.					

7. OTHER COMMENTS

REPORTER DETAILS Name: _____ Signature:	Qualification : _____ Number of pages:	Address: _____ _____ _____ Date : ___/___/____ (dd/mm/yyyy)	Phone number: _____ Fax: _____ Email: _____

Nordic Group uses health data file collected for pharmacovigilance, medical information and post-marketing medicinal products quality purposes. Those data are kept for a compliant period required by law. You have the right to access and correct by contacting us at pv@nordicpharma.com. You can also make a complaint to our Data Protection Officer by email at dataprivacy@nordicpharma.com and to the CNIL (https://www.cnil.fr) in the event of infringement of your rights. For more information visit our Nordic website (http://www.nordicpharma.fr).