Reporting Suspected Adverse Drug Events Associated with Pregnancy or Breastfeeding

Send to: CHEPLAPHARM Arzneimittel GmbH
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Email: drugsafety@cheplapharm.com

Privacy notice: As a pharmaceutical company we are legally bound to process and save information on possible side effects of our medicinal products and forward such information to competent authorities. Details can be found at: https://www.cheplapharm.com/datenschutz/.

1. INFORMATION MOTHER

Initials*	
Date of birth (DD-MM-YY)*	☐☐☐☐☐☐
Age*	
Ethnic background	
First day of most recent period	
Expected date of delivery (DD-MM-YY)	☐☐☐☐☐☐
Fertility treatment	no ☐ yes ☐ If yes, please give more information in section 5.
High-risk pregnancy	no ☐ yes ☐ If yes, please give more information in section 5.

* Please provide at least one of the above mentioned identification details in order to be able to report the side effect(s) to competent authorities effectively.

2. MATERNAL DRUG EXPOSURE **DURING** PREGNANCY OR BREASTFEEDING PERIOD

Brand name/Active substance Batch number	Manufacturer	Strength, Dose/Amount	Route of application	Dates of use (From/To)	Indication(s)	PW
I.						
II.						
III.						
IV.						

3. MATERNAL DRUG EXPOSURE **BEFORE** PREGNANCY

Brand name/Active substance Batch number	Manufacturer	Strength, Dose/Amount	Route of application	Dates of use (From/To)	Indication(s)
I.					
II.					
III.					
IV.					

4. MEDICAL HISTORY OF MOTHER

Relevant medical history and comments (use of nicotine or alcohol, allergies, pacemaker, implants, restricted diet, metabolic deficiencies, genetic predisposition, previous abortions, e.g.):

5. PRENATAL DIAGNOSTICS INDICATING POSSIBLE CONGENITAL DEFECTS

If yes, which tests have been performed?

no ☐
yes ☐

6. ADVERSE DRUG EVENT

Diagnosis:

Start date ☐☐☐☐☐☐ Day Month Year

End date ☐☐☐☐☐☐ Day Month Year

Further description of adverse event (symptoms, clinical signs, tests, related laboratory results including dates, affected body parts, therapy programme and treatment progress):

Seriousness of adverse event
(Check all that apply):
- ☐ Initial or prolonged hospitalization
- ☐ Disability or permanent damage
- ☐ Congenital anomaly/Birth defects
- ☐ Life-threatening
- ☐ Death

Outcome of adverse event:
- ☐ Ongoing
- ☐ Recovering
- ☐ Fully recovered
- ☐ Permanent
- ☐ Unknown
- ☐ Date of death: Day Month Year

Autopsy: no ☐ yes ☐

7. PREGNANCY OUTCOME

Multiple birth	no ☐	yes ☐	If yes, number of fetuses:
Date of birth or abortion (DD-MM-YY)		live birth ☐	abortion ☐ stillbirth ☐
Sex of the child	male ☐	female ☐	Initials:
Gestation at time of delivery in weeks			
Height in cm			
Weight kg lb			
Head circumference in cm			
APGAR score	1 min:	5 min:	10 min:
Delivery	spontaneous ☐	cesarian ☐	other
Congenital defect	no ☐	yes ☐	If yes, which?

8. FURTHER INFORMATION

9. TREATING PHYSICIAN (if differing from reporter)

Name, Medical specialist title:

Phone number/Email:
Address:

10. DATA OF THE REPORTING PERSON

Name, Surname*:

Additionally reported to:

Function*:
- ☐ Physician
- ☐ Pharmacist
- ☐ Patient/Relative

Address*:

Date, Signature: Day Month Year

Phone*:
Email*:

* Please provide the name of the reporter and (if the reporter is a health professional) the job title. For further enquiries it is necessary to provide at least one possibility to contact, i.e. phone, email and/or postal address.

Should the space be not sufficient, please use the backside of the page.