Adverse Drug Event Reporting Form

Send to: CHEPLAPHARM Arzneimittel GmbH
Ziegelhof 24, 17489 Greifswald
Phone: 03834 - 3914 329 Email:
Fax: 03834 - 3914 349 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/rechtliche-hinweise/datenschutz/

I. PATIENT INFORMATION

Initials*	Date of Birth*	Age*	Sex*		Study
☐☐☐	☐☐ ☐☐ ☐☐☐☐		☐ male	Height: cm	no ☐
First/Middle/Last name	Day Month Year		☐ female	Weight: kg	yes: ☐

* 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.

Relevant medical history, including pre-existing medical conditions:

II. 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 hospitalisation
- ☐ 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: ☐ yes ☐ no

III. MEDICINAL PRODUCTS (Application prior to adverse event)

Brand name/ Active substance	Manufacturer	Dosage	Route of application	Dates of use (From/To)	Indication	Causality suspected
I.						☐ yes ☐ no
II.						☐ yes ☐ no
III.						☐ yes ☐ no
IV.						☐ yes ☐ no

If you do not suspect a causal relationship between the reported adverse event and the CHEPLAPHARM product, please indicate the possible cause of effect (e.g. primary disease or comorbidity):

IV. COMMENTS

V. DATA OF THE REPORTING PERSON

Name, Surname*:

Additionally reported to:

Date, Signature: ☐☐ ☐☐ ☐☐☐☐ (Day Month Year)

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

Address*:

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.