

<b>Adverse Drug Event Reporting Form</b>	<b>Send to:</b> CHEPLAPHARM Arzneimittel GmbH Ziegelhof 24, 17489 Greifswald Phone: 03834 - 3914 329 Email: Fax: 03834 - 3914 349 drugsafety@cheplapharm.com
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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* <input style="width: 100%; height: 20px;" type="text"/>	Date of Birth* <input style="width: 100%; height: 20px;" type="text"/>	Age*	Sex* male female	Height: cm Weight: kg	Study no yes:
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\* 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	End Date
	<input style="width: 100%; height: 20px;" type="text"/>	<input style="width: 100%; height: 20px;" type="text"/>
	Day Month Year	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):

<b>Seriousness of adverse event</b> (Check all that apply): <input type="checkbox"/> Initial or prolonged hospitalisation <input type="checkbox"/> Disability or permanent damage <input type="checkbox"/> Congenital anomaly/Birth defects <input type="checkbox"/> Life-threatening <input type="checkbox"/> Death	<b>Outcome of adverse event:</b> <input type="checkbox"/> Ongoing <input type="checkbox"/> Recovering <input type="checkbox"/> Fully recovered <input type="checkbox"/> Permanent <input type="checkbox"/> Unknown Date of death: <input style="width: 100%; height: 20px;" type="text"/> <div style="text-align: center;">Day Month Year</div>
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Autopsy:  yes  no

**III. MEDICINAL PRODUCTS (Application prior to adverse event)**

Brand name/ Active substance/ Batch number	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*:	Function*: Physician Pharmacist Patient/Relative	Address*:
Additionally reported to:		
Date, Signature: <input style="width: 100%; height: 20px;" type="text"/>		Phone*: Email*:
Day Month Year		

\* 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.