GEDEON RICHTER ROMÂNIA S.A.

Adverse Event Reporting

I. PATIENT AND ADVERSE EVENT

1. Patient initials:	2. Date of birth (day, month, year) or age:	3. Patient gender ❑ Male ❑ Female	4. Onset date (day, month, year):	5. Cessation date (day, month, year):

6. Event description:	7. Criteria of seriousness: ❑ death ❑ life threatening ❑ hospitalization/prolongation of hospitalization ❑ disability or permanent damage ❑ congenital anomaly / Birth defect ❑ other serious (important Medically Events)

8. Did the adverse reaction improve when the drug was discontinued? ❑ yes ❑ no ❑ not applicable	9. Did the adverse reaction reappear, when the drugs was readministered? ❑ yes, date: ❑ no ❑ not applicable

10. Please select an outcome for side effect:
❑ Recovered ❑ Recovered with some lasting effects ❑ Getting better ❑ Side effect continuing ❑Getting worse ❑ caused death date: ❑ unknown
❑ other (please give details in the box provided above)

II. SUSPECT DRUG(S) INFORMATION

11. Suspect drug(s) (include generic name):	12. Route of administration (p.o., i.m., i.v., etc.):
13. Indication(s) for use:	14. Daily dose:
15. Therapy dates or duration (start date, end date):	16. Was the drug(s) discontinued? ❑ yes, date: ❑ no

III. CONCOMITANT DRUG(S) AND MEDICAL HISTORY

17. Concomitant drugs and dates of administration:

Product description	Dose, route of administration	Therapy start/end date	Indication

18. Other relevant history:

GEDEON RICHTER ROMÂNIA S.A.

IV. REPORTER DETAILS

19a. Reporter name:	
19b. Reporter type: ❑ doctor, ❑ pharmacist, ❑ nurse, ❑ other:	
19c. Reporter workplace, address:	
19d. Reporter phone number:	20. Reporting date (day, month, year):

6. PATIENT AND ADVERSE EVENT (continuation):

17. CONCOMITANT DRUG(S) AND MEDICAL HISTORY (continuation):

I expressly and unequivocally manifest my agreement that my personal data be used and processed by the Richter Group, by automated/manual means for pharmacovigilance purposes.
I agree that the Richter Group administers safely and confidentially the data recorded for the duration necessary to achieve the stated purpose and in case of need to communicate them to the health authorities.

☐ *YES* ☐ *NO*

.....
reporter signature

Please download this reporting form, fill in and send it via email, post or fax to the following address:
Gedeon Richter Romania Ltd.
Pharmacovigilance Office
Cuza Voda street, 99-105
540360, Targu Mures, Romania
e-mail: pharmacovigilance@gedeon-richter.ro
Fax number: 0040-265-257011