

# Adverse Event Reporting Form



Country where Adverse Event occurred: \_\_\_\_\_

Type of Report:     initial                     follow - up

**Patient Data** (fill in at least one)

Initials	Date of Birth, or Age	Sex	Height	Weight
			cm	kg

**Seriousness** (Mark All Appropriate)

None appropriate = **Non-serious**

- Result in death                     Life-threatening                     Caused / prolonged hospitalisation  
 Disabling/ Incapacitating                     Congenital anomaly                     Clinically significant / required intervention

**Adverse Event**

Description	Onset Date	End Date

**Drug Therapy**

Suspected Drug (Product name & Active Substance)	Batch Number	Dose	Route (iv, po)	Start Date - End Date	Indication	Action taken (dose unchanged /reduced, withdrawn, unknown)

Provide as much information as possible; use an extra sheet if not enough space

**Relevant Medical Information and Concomitant Treatment** (e.g. Diagnoses, Treatments, Family History, Risk Factors, Allergies, Nicotine or Alcohol Abuse, Occupation, etc.)

**Causality:**     Definite     Probable     Possible     Unlikely     Not related     Not assessable

**Outcome:**     Recovered/Resolved     Recovered/Resolved with Sequelae     Ongoing     Improvement  
 Deterioration     Death     Not Assessable

**Name and Address of Reporter (including e-mail or phone number)**

**Date and Signatur:**

Transmit immediately to:    **E-Mail: [drugsafety@everpharma.com](mailto:drugsafety@everpharma.com)**    **Fax: +43 7665 20555 ext 910**