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**BUNDESMINISTERIUM FÜR  
GESUNDHEIT UND FRAUEN**



Eingangsstempel

An das  
Bundesministerium für Gesundheit  
und Frauen  
Abteilung III/A/1  
Radetzkystraße 2  
A-1031 Wien  
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## **Report of Suspected Unexpected Serious Adverse Reactions (SUSARs)**

For official use:

Date of receiving the report:	Date of request for additional information:	Competent Authority, Ethic Committee registration number:
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To be filled in by the sponsor:

### **1. Clinical trial identification:**

Eudract number:

Sponsor's trial protocol number:

### **2. Subject's details :**

Sponsor's subject identification number:

Initials, if applicable:

Gender:

male

female

Age and/or date of birth:

Weight:

Height:

### 3. Suspected investigational medicinal product(s) :

Name of the IMP or brand name as reported:

International non-proprietary name (INN):

Batch number:

Indication(s) for which suspect investigational medicinal product was prescribed or tested:

Dosage form and strength:

Daily dose and regimen  
(specify units e.g. mg, ml, mg/kg):

Route of administration :

Starting date and time of day:

Stopping date and time,  
or duration of treatment:

Unblinding :

yes       no       not applicable

Results:

\* Investigator's causality assessment:

\* Sponsor's causality assessment:

\* Comments, if relevant (e.g. causality assessment if the sponsor disagrees with the reporter; concomitant medications suspected to play a role in the reactions directly or by interaction; indication treated with suspect drug(s)):

#### 4. Other treatment(s) :

For concomitant medicinal products (including non prescription/OTC medicinal products) and non-medicinal product therapies, provide the same information as listed above for the suspected investigational medicinal product.

Name of the IMP or brand name as reported:

International non-proprietary name (INN):

Batch number:

Indication(s) for which suspect investigational medicinal product was prescribed or tested:

Dosage form and strength:

Daily dose and regimen  
(specify units e.g. mg, ml, mg/kg):

Route of administration :

Starting date and time of day:

Stopping date and time,  
or duration of treatment:

Unblinding :

yes       no       not applicable

Results:

\* Investigator's causality assessment:

\* Sponsor's causality assessment:

\* Comments, if relevant (e.g. causality assessment if the sponsor disagrees with the reporter; concomitant medications suspected to play a role in the reactions directly or by interaction; indication treated with suspect drug(s)):

## 5. Details of suspected Adverse Drug Reaction (s) :

### **Full description of reaction (s)**

including body site and severity, as well as the criterion (or criteria) for regarding the report as serious should be given. In addition to a description of the reported signs and symptoms, whenever possible attempts should be made to establish a specific diagnosis for the reaction:

Reaction(s) in MedDRA terminology  
(lowest level term):

Start date (and time) of  
onset of the reaction:

Stop date (and time) or  
duration of the reaction:

De-challenge and  
re-challenge information:

Setting (e.g. hospital, out-patient clinic,  
home, nursing home):

### **Outcome :**

Information on recovery and any sequelae:

What specific tests and/or treatment may  
have been required and their results:

For a fatal outcome, cause of death and a  
comment on its possible relationship to the  
suspected reaction should be provided:

Any autopsy or other post-mortem findings  
(including a coroner's report) should also  
be provided when available:

### **Other information :**

anything relevant to facilitate assessment of the case, such as  
medical history including allergy, drug or alcohol abuse ; family history ; findings  
from special investigations:

## 6. Details on reporter of event/suspected ADR :

Name:

Address:

Telephone number:

Profession (speciality):

## 7. Administrative and Sponsor details:

Date of this report:

### Source of report:

From a clinical trial (provide details if not in Eudract, from the literature (provide copy):

Spontaneous:

Other:

Date event report was first received by sponsor:

Country in which reaction occurred:

### Type of report filed to authorities :

initial  follow-up (first, second, etc):

Name and address of sponsor/manufacturer/company:

Name, address, telephone number and fax number of contact person in reporting sponsor:

Identifying regulatory code or number for marketing authorisation dossier or clinical investigation process for the suspected product (for example IND number, NDA number):

Case reference number (sponsor's/manufacturer's identification number for the case) (this number must be the same for the initial and follow-up reports on the same case):

Date:

Print Name:

Signature: