



Patient Safety AstraZeneca Switzerland ADVERSE EVENT REPORT FORM

Please return to:

Email: patientsafety.ch@astrazeneca.com Fax: 041 725 71 57

1. Patient Details (Please ensure patient anonymity)

Patient Initials

Year of Birth or Age

☐ Male☐ Female

Ethnic Origin e.g. Caucasian

Weight

Height

Reported to regulatory

☐ Yes☐ No

For AZ Use only

Date report received by AZ

Does this report fulfill the local criteria for an expedited report?

☐ Yes☐ No

2. Reporter Information (e.g. Healthcare Professional, etc.)

Reporter's Name

Reporter's Address & Email Address

Country

Phone Number

Reporter's qualification:

☐ Physician☐ Pharmacist☐ Other health professional*☐ Non health Professional*

*Please specify

Reporter's Signature:

Date:

3. Suspect Drug(s)

Please give brand name if known

Lot No.

Indication

Dose, units, and frequency

Route

Start Date

Stop Date

Action Taken with suspect drug

4. Adverse Event Description

(Diagnosis of Adverse Event(s). If diagnosis not known, give symptom(s))

Start Date

Stop Date or Duration

Intensity

* Outcome

			<input type="checkbox"/> Mild	<input type="checkbox"/> Mod.	<input type="checkbox"/> Severe	
			<input type="checkbox"/> Mild	<input type="checkbox"/> Mod.	<input type="checkbox"/> Severe	
			<input type="checkbox"/> Mild	<input type="checkbox"/> Mod.	<input type="checkbox"/> Severe	

Did AE improve after stopping or reducing drug?

☐ Yes☐ No☐ n/a

Did AE reappear after reintroduction?

☐ Yes☐ No☐ n/a

* Outcome Key

1 = Recovered/Resolved

2 = Recovering/Resolving

3 = Not Recovered/Not Resolved

4 = Recovered/Resolved with Sequelae

5 = Fatal

6 = Unknown

5. Please provide any further relevant information about the Adverse Event including any investigations carried out, laboratory test results, and treatment received. Please use additional information box on page two if needed.

(Please ensure patient anonymity is maintained throughout your report)

Do you consider that there is a reasonable possibility that the event may have been caused by the suspect drug?

☐ Yes☐ No

Reason

6. Seriousness: Is the Adverse Event serious?

☐ Yes☐ No

If yes, please select criteria below:

Death

Immediately Life-Threatening

In-patient Hospitalization/
Prolonging Existing Hospitalization☐ Resulting in Persistent/
Significant Disability or Incapacity

Congenital Abnormality / Birth Defect

Significant Medical Event

If 'Death', Specify Cause:

Date of Death:

Post Mortem: Autopsy Performed?

Yes

No

(If 'Yes', Please Attach Findings)

7. Relevant Medical History / Concurrent Diseases

Please also include drug reactions, allergies, environmental factors, and (or) drug & alcohol abuse
(Please ensure patient anonymity is maintained throughout your report)

8. Concomitant Drug(s)

(Exclude drugs used to treat the event)

Indication

Daily Dosage

Route

Start Date

Stop Date

9. Additional Information

(Please ensure patient anonymity is maintained throughout your report)

Please attach copies of any relevant investigations such as laboratory tests / autopsy records. Please ensure patient anonymity is maintained by blanking out necessary fields on the copy.

Thank you for your assistance in following up on this case.

If you would like acknowledgement of the receipt of this form please provide the relevant contact details next to your preferred method of acknowledgement.

EMAIL: _____ TELEPHONE: _____

ADDRESS: _____