Report of Suspected Adverse Experience (AE)

MSD

LRN:

Patient

Initials Gender: ♀ ☐ ♂ ☐ Age: Weight: kg Is patient pregnant? ☐ yes ☐ no weeks

Adverse experience information

1)	Date of onset:	Duration:
2)	Date of onset:	Duration:
3)	Date of onset:	Duration:
4)	Date of onset:	Duration:

Check all event criteria appropriate to AE:

☐ Death, date: Cause: Was autopsy performed? ☐ yes ☐ no (If available, please provide copy of autopsy results)
☐ Life threatening ☐ Persistent or significant disability/incapacity ☐ Cancer
☐ Hospitalization / prolonged hospitalization ☐ Congenital anomaly ☐ none of the above
☐ Overdose, received dose: ☐ Medically important*

* Event that without treatment would have led to one of the above serious consequences according to medical judgment.

Suspect drug information

Product	Route	Daily Dose	Indication	Start Date	Stop Date	Batch /Lot no.	Expiry Date

Actions taken:

☐ Treatment stopped
☐ Treatment interrupted from to
☐ Dose reduction
☐ Dose increase
☐ None

Further course after therapy withdrawal/reinitiation:

Did experience abate after stopping therapy?
Yes ☐ No ☐

Did experience reappear after reintroduction
Yes ☐ No ☐ Therapy restarted on:

Causality assessment

Do you suspect a causal relationship between the adverse reactions and the MSD product?

☐ YES ☐ NO

Concomitant medication

Product	Route	Total Daily Dosage	Start Date	Stop Date	Indication

Short description of the case
including treatment of the ADR (if applicable, please provide start and stop date of the therapy):

Click here to enter text.

Outcome:

☐ fatal ☐ recovered/resolved with sequelae ☐ recovering/resolving ☐ worsening
☐ not recovered/Not resolved ☐ recovered/resolved ☐ unknown

Concurrent Conditions/Concomitant Illnesses (Medical conditions that developed prior to initiation of drug therapy and were unresolved at the time of the first adverse event):

Click here to enter text.

Past Medical History (Events preceding the occurrence of the adverse event - list any pertinent information including past drug reaction or allergies, start and stop dates):

Click here to enter text.

Relevant lab results / diagnostic criteria / X-ray findings			
Date	Parameters	Value / Normal value	Comment

Do you agree to be contacted for additional questions in case of missing information?

Yes ☐ No ☐

Reporter name: _____

Location/date: _____

Signature: _____

MSD Merck Sharp & Dohme AG
Pharmacovigilance
Werftestrasse 4
6005 Luzern
Telefon 058 618 33 10
Telefax 058 618 39 50

We would like to inform you that any personal data provided by you will be used solely for recording and processing your inquiry and treated by MSD with full respect of your and your patient's privacy. Please read more about the privacy commitment at www.msd.ch