

Otsuka Pharmaceutical India Private Limited

SUSPECTED ADVERSE DRUG REACTION (ADR) REPORTING FORM

Reporter details*

Name: _____

Professional Address: _____

Pin code: _____

E-mail: _____

Contact No: _____ Occupation: _____

Signature: _____

Patient details*

Patient Initials: _____

Age: _____

Date of Birth: _____

Weight (in kg.): _____

Sex: Male Female Other

Suspected Adverse Reaction*

Date of reaction Started: _____ Date of recovery: _____

Describe the reaction and its management (if applicable)

Suspected Drug*

Sr. No.	Name of drug (Brand/Generic)	Batch No.	Exp. Date	Dose and route	Frequency	Therapy dates		Reason for use /Indication
						Date Started	Date Stopped	

Concomitant Drug (including self-medication and herbal remedies (if applicable) with therapy dates (Exclude those used to treat reaction))

Sr. No.	Name of drug (Brand/Generic)	Start Date	Stop Date	Dose and route	Reason for use/Indication

Action taken after reaction (please tick)

Sr. No.	Drug Withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown

Reaction abated after drug stopped or dose reduced

Reaction reappeared after reintroduction

Sr. No.	Yes	No	Unknown	NA	Reduced Dose	Yes	No	Unknown	NA	If reintroduced Dose

Relevant tests/ Laboratory data with dates:

Other relevant history including pre-existing medical condition:

Seriousness of the reaction:

- No if Yes (please tick anyone)
- Death on date Congenital-anomaly
- Life threatening Disability
- Hospitalization-Initial/Prolonged Other Medically important

Outcomes:

- Recovered Recovering
- Not Recovered Fatal
- Recovered with sequelae Unknown

Causality Assessment:

Date of this Report:

You can share this form or details by email (scanned copy), telephone call, Fax or by post. Following are contact details

Email Id: PV.CORP-AMD@OTSUKAPHARMA.IN

Website : <http://www.otsukapharma.in/>

Telephone No.: **+9179 6621 6051**

Fax: **+91 79 6621 6050**

Postal Address:

Otsuka Pharmaceutical India Pvt. Ltd.
21st Floor, B-Block, Westgate,
Nr. YMCA, SG Highway,
Ahmedabad - 380 015. India

1. Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent.
2. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.
3. Submission of an ADR report does not have any legal implication on the reporter.
4. All healthcare professionals (Clinicians, Dentists, Pharmacists and Nurse etc.) as well as patients, relatives or any other person can report suspected adverse drug reactions.

*Mandatory Fields for suspected ADR Reporting Form

Thank You for Reporting