Hayat Pharmaceutical Ind. Co.

Adverse Event Form

Only HPI (Internal) Coding number: F-PV05001/01

Initial: ☐ Follow-up: ☐ Local reference number*:

Patient Data

Initials (first, last):	Country:	Date of Birth(DD, MM,YYYY):	Age(years):
Gender: ☐ M ☐ F	Weight: Kg	Height: cm	

Suspect Medication

Trade Name: | Active Substance: | Batch No.:

Indication	Dosage	Frequency(e.g. daily)	Start date of Treatment	End date of treatment	Date of the last administration before the AE

Therapy continued? ☐Yes ☐No

Dosage reduced due to AE? ☐Yes ☐No

If yes, new dosage:

Administration:

☐ oral Dosage form: ……

☐ other Description: ……

Lab Test

To be Stated, if available

Data on Adverse Event (AE)

Adverse Event (AE):

Description of the AE(any symptoms/signs, progression, reappearance after reintroduction, baseline/post-event investigations-please attach investigation results if appropriate):

AE start date: (DD-MM-YYYY) AE end date: (DD-MM-YYYY) AE duration:

How long after the administration the AE occurred?

Was the AE treated with medication? ☐ No ☐ Yes

Name of treatment	Route/Form	Start date	Stop date	Daily Dose

Any other treatment:

* for Hayat Pharma use only

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Classification of Adverse Events	☐Life-threatening ☐ Permanent or significant disability/Capacity impairment ☐ Hospitalization ☐Prolongation of an existing hospitalization ☐Congenital anomaly / Birth defect ☐Medically important event (please specify): _____
Causality	Causal relationship between suspected medication and AE: ☐Not Related ☐ Related
Medical History	**Information on medical history** (any diseases that the patient has for example: Diabetes, Hypertension, etc.) Any Known Risk Factors: ☐ Alcohol use ☐ Smoking ☐ Obesity ☐ Metabolic disorder ☐ Diet ☐ Pacemaker ☐ Radiation therapy ☐ Drug abuse ☐ Drug dependent ☐ Contraceptives ☐ Other (specify) Any Known Allergies Is Patient Pregnant ☐ No ☐ Yes Trimester: ☐ 1st ☐ 2nd ☐ 3rd

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Concomitant Medication

Concomitant Medication (any other drugs that the patient is taking)

Name of Preparation	Indication	Daily Dose	Route of administration	Start Date of treatment	End Date of treatment

* if required, please complete a separate page or attach the patient's drug list

Other Comments

Reporter Information

Name:
Address:
Country:
Phone Number:
Email:
Signature of the person notifying the AE:
Report Source:
☐ Patient ☐ Doctor ☐ Pharmacist ☐ Others: _____
Date:

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