Pharmacovigilance (PhV) Division

Adverse Drug Reactions Reporting Form

Reporting Adverse Events is vital to the safe use of the drug. Adequate information provided by patients enables the company to assess the safety of its pharmaceutical products on the market.
The information in this report is confidential and totally protected including both the identity of the patient and the report provider.
Data marked with (*) are mandatory.

Report Date*

Reporter Details (*The Person who reports the Event*)

Physician ☐ Pharmacist ☐ Nurse ☐ Patient ☐ Patient's Relative/Friend/caregiver ☐
Other (Please specify)

1) Name*	2) Specialty (*If Physician*)*	
3) Telephone/Mobile*	4) Address	5) e-mail
6) Is it acceptable to contact you if we have more questions about this report?	Yes ☐	No ☐

Patient Information

1) Patient Name/Initials*	2) Country*	3) Date of Birth*

4) Gender* (Male☐ / Female☐)
For Female (Pregnant☐ / Planning for Pregnancy☐ / Breastfeeding☐ / Unknown☐)

Suspected Drug (s) Information

Product Name (Trade or Generic Name / Concentration) *	Daily Dose and Route*	Used For*	Start Date*	Stop Date*	Batch No.

1) How Many **Doses** have been taken from the start of treatment until the 1st Adverse Event occurred?
2) Was the **Dose** changed after the Adverse Event occurred?
(Not Changed☐ / Dose Reduced☐ / Dose Increased☐ / Drug Stopped☐ / Unknown☐).
If the **Dose Reduced** or **Increased** or the **Drug Stopped**
Have the Adverse Event **improved** as a result of the action taken? (Yes☐/ No☐/ Unknown☐).
If **Yes**
Has the patient **returned** to take the drug with the same original Doses? (Yes☐ / No☐/ Unknown☐).
If **Yes**
Did the Adverse Event **returned**? (Yes☐/ No☐/ Unknown☐).

Adverse Drug Event

1) Please **Describe** the Adverse Event *

2) Adverse Event **Starting** Date*	3) Adverse Event **Ending** Date*

4) **Seriousness** of the Adverse Event * (*according to the reasons of seriousness listed below*)
(Death☐ Life-threatening ☐ Disablity☐ Hospitalization- initial ☐ Hospitalization-prolonged ☐
Congenital abnormality ☐ Medical intervention required to treat that adverse event ☐ Not serious ☐).
5) What is the **Current Outcome** of this Adverse Event?
(Recovered completely☐ / Recovered with lasting effects☐ / Persisting☐/ Unknown☐).
In case of Death
- Date of Death - Autopsy Report (*If available please attach*)
In case of Hospitalization
- Admission Date - Discharge Date

Concomitant Drug(s) Information

(*Please list the medications you have taken **within a Month before** adverse Event(s) occur*)

Product Name (Trade or Generic Name / Concentration)	Daily Dose and Route	Used For	Start Date	Stop Date

Utopia Medical Representative Details

1) Name	2) Telephone	3) Scientific office

UTOPIA Head Office
4-Hassan Maamoun Tower-Nasr City-Cairo-Egypt.

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