Adverse Drug Reaction (ADR) reporting form (Initial and follow up)

Enter dates in format DD/MM/YYYY throughout the form

Case ID:	Date of receipt of information:
☐ Initial report ☐ Follow up report	Follow up information requested ☐ Yes ☐ No

1. Patient Information **Data available** ☐ **No** ☐ **Yes (please complete the section below)**

Initials	Gender:	☐ F ☐ M	Age:		Estimated date of delivery:
	Weight:	kg	Age Group:		
	Height:	cm	Date of Birth:		
	Pregnancy:	☐ No ☐ Yes	Trimester:	☐ 1st ☐ 2nd ☐ 3rd	
	In pregnancy, please fill the pregnancy report form.				

Any additional relevant patient information (e.g. medical history such as autopsy report, hospital discharge summary, laboratory values, concomitant conditions or concomitant medication)

2-Information on the adverse drug reaction :

ADR 1*	ADR 2	ADR3	ADR 4
Date :	Date:	Date :	Date :

ADR (s) Description:

Dates	Start Date: (DD /MM /YYYY) Stop Date: (DD /MM /YYYY)
Outcome	☐ Ongoing ☐ Recovering ☐ Recovered without Sequelae ☐ Recovered with Sequelae (specify): ☐ Fatal/Death ☐ Unknown
Seriousness	☐ Non-serious ☐ Serious (If serious, please complete following):

	☐ Death Date: Autopsy ☐ No ☐ Yes (please provide copy of autopsy report) ☐ Life-threatening ☐ Hospitalization (> 24 h) ☐ Prolongation of existing hospitalization (> 24 h) ☐Persistent or significant disability/incapacity ☐ Congenital anomaly/Birth defect ☐ Medically important (e.g., patient requires intervention to prevent one of outcomes listed above)
Causal Relationship	☐ Certain ☐ Probable/ Likely (reasonable time relationship; unlikely to be attributed to other plausible cause) ☐ Possible (reasonable time relationship; could be attributed to other plausible cause) ☐ Unlikely ☐ Not related ☐ Un-assessable (To be used for, e.g. Pregnancy, medication errors etc.,)
Corrective therapy (treatment required to treat the reported ADR?)	☐ No ☐ Yes (specify medication administered for treatment):

Name of product	Daily Dose	Route/Form	Start Date: (DD /MM /YYYY)	Stop Date : (DD /MM /YYYY)
Name of product	Daily Dose	Route/Form	Start Date: (DD /MM /YYYY)	Stop Date: (DD /MM /YYYY)

3-Suspect products :

	Product name	Active ingredient	Dosage	Route of administration	Start date	End date	Indication
1							
2							
3							

Action taken with suspected products?	- Withdrawn due to Adverse drug reaction (ADR): ☐ No ☐ Yes (specify): ☐ Resolution of suspected ADR ☐ Improvement of suspected ADR ☐ No improvement of suspected ADR - Reintroduced ☐ No ☐ Yes (specify): ☐ Recurrence of suspected ADR ☐ Dosage reduced due to ADR? ☐ Indicate the new dose

4-Reporter details				
☐ Physician ☐ Patient/consumer/family member ☐ Other, specify:	Name	Address	Country	Phone/ Fax/ Email
Is the report associated with a product technical complaint (PTC) ☐ **Yes** ☐ **No**				
Comments :				

Privacy Notification:

The information in this report is confidential and totally protected including both the patient and the reporter.

*Reporting for ADRs is vital for safety usage of the drug. Enough information will help to evaluate the safety of the drug.

Please provide all available information and send completed form to Memphis Company:

E-mail: PV@memphis.com.eg

Tel.no: 202/22829880

Attach any applicable supporting documentation if applicable (such as pictures, autopsy report, hospital discharge summary, laboratory values).