


SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by healthcare professionals

Themis Medicare Ltd. 11/12, Udvoḡ Nagar Industrial Estate. Sv Road, Goregaon(W), Mumbai – 400090 Ph: 9805286542, 022-67607080 (Ext-359) Email: drugsafety@themismedicare.com			TML ADR 2018.....	
A. Patient Information			12. Relevant tests / laboratory data with dates	
1. Patient Initials -----	2. Age at time of Event or date of birth -----	3. Sex <input type="checkbox"/> M <input type="checkbox"/> F 4. Weight ___ Kgs	13. Other relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc)	
B. Suspected Adverse Reaction			14. Seriousness of the reaction	
5. Date of reaction stated (dd/mm/yyyy)			<input type="checkbox"/> Death (dd/mm/yyyy)_____ <input type="checkbox"/> Congenital anomaly	
6. Date of recovery (dd/mm/yyyy)			<input type="checkbox"/> Life threatening <input type="checkbox"/> Required intervention	
7. Describe reaction or problem			<input type="checkbox"/> Hospitalization-initial to prevent permanent or prolonged impairment / damage	
			<input type="checkbox"/> Disability <input type="checkbox"/> Other (specify)	
			15. Outcomes	
			<input type="checkbox"/> Fatal <input type="checkbox"/> Recovering <input type="checkbox"/> Unknown	
			<input type="checkbox"/> Continuing <input type="checkbox"/> Recovered <input type="checkbox"/> Other (specify)_____	

C. Suspected medication(s)

S. No	8. Name (brand/generic)	Manufacturer (if known)	Batch No/ Lot No. (if known)	Exp. Date (if known)	Dose used	Route used	Frequency	Therapy dates (if known give duration)		Reason for use of prescribed for
								Date started	Date stopped	
I.										
II.										
III.										
IV.										
Sl.No As per C	9. Reaction abated after drug stopped or dose reduced					10. Reaction reappeared after reintroduction				
	Yes	No	Unknown	NA	Reduced dose	Yes	No	Unknown	NA	If reintroduced dose
I.										
II.										
III.										
IV.										

11. Concomitant medical product including self medication and herbal remedies with therapy dates (exclude those used to treat reaction)	D. Reporter (see confidentiality section in first page)
	16. Name and Professional Address: _____ Pin code : _____ E-mail _____ Tel. No. (with STD code): _____ Occupation _____ Signature _____
	17. Causality Assessment
	18. Date of this report (dd/mm/yyyy)