SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

(For Voluntary reporting of Adverse Drug Reactions)

Themis Medicare Ltd.
11/12, Udyog Nagar Industrial Estate, SV Road,
Goregaon(W), Mumbai – 400104
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TML ADR yyyy…….

Report: Initial / Follow up
Report Type: Spontaneous / Clinical
Themis Awareness Date: dd/mmm/yyyy:

A. Patient Information

1.Patient Initials ----------	2.Age at time of Event or date of birth - ----------	3.Sex ☐M ☐F 4.Weight___Kgs

12. Relevant tests / laboratory data with dates

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

5. Date of reaction started (dd/mm/yyyy)
6. Date of recovery (dd/mm/yyyy)
7. Describe reaction or problem

14. Seriousness of the reaction
☐ Death (dd/mm/yyyy)_____ ☐ Congenital anomaly
☐ Life threatening ☐ Required intervention
☐ Hospitalization-initial or prolonged ☐ to prevent permanent impairment / damage
☐ Disability ☐ Other (specify)

15. Outcomes
☐ Fatal ☐ Recovering ☐ Unknown
☐ Continuing ☐ Recovered ☐ Other (specify)___

C.Suspected medication(s)

S. No	8. Name (brand and /or generic name)	Manufacture (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.										
V.										
VI.										
VII.										

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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	
		16. Name and Professional Address:_____ _____ Pin code: _____ E-mail_____ Mob/ Tel. No.: _____ Occupation _____ Signature _____	
		17. Causality Assessment	18. Date of this report (dd/mm/yyyy)