

ADVERSE DRUG REACTION REPORTING FORM

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM											
For VOLUNTARY reporting of Adverse Drug Reactions by Healthcare Professionals											
Regulatory Department: Megasy's Biotech Private Limited Kinfra Small Industries Park, Kinfra Park, Koratty, Thrissur, Kerala-680309, India Email: info@megasysbiotech.com Contact: 0480 2735991/2733158 (Monday to Saturday between 8.30 am to 5.00 pm, except on public holidays)							FOR MEGASYS USE ONLY				
							Report No.:				
							Report Type:		☐ Initial	☐ Follow up	
							12. Relevant test/laboratory data with dates				
A. PATIENT INFORMATION											
1. Patient Initials-		2. Age at time of Event or Date of Birth-		3. ☐ M ☐ F ☐ Others		4. Weight _____ Kgs 4. a) Height _____ Cm		13. Relevant medical/medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic or renal dysfunction, past surgery etc)-			
B. SUSPECTED ADVERSE REACTION							14. Seriousness of the reaction: No ☐ if Yes ☐ (please tick anyone)				
5. Event/Reaction start date (dd/mm/yyyy)-											
6. Event/Reaction stop date (dd/mm/yyyy)-							☐ Death (dd/mm/yyyy)		☐ Congenital anomaly		
6 (A). Onset Lag Time-							☐ Life threatening		☐ Disability		
7. Describe Event/Reaction with treatment details, if any-							☐ Hospitalization/Prolonged		☐ Other Medically important		
							15. Outcomes				
							☐ Recovered		☐ Fatal		
							☐ Recovering		☐ Recovered with sequelae		
							☐ Not recovered		☐ Unknown		
C. SUSPECTED MEDICATION(S)											
S.No.	8. Name (Brand/Generic)	Manufacturer (if known)	Batch No./Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (OB, BD etc.)	Therapy		Indication	Casualty Assessment
								Date Started	Date Stopped		
i											

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ii											
iii											
iv*											
S. No as per C	9.Action Taken (please tick)					10.Reaction reappeared after reintroduction (please tick)					
	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	Yes	No	Effect Unknown	Dose (if reintroduced)	
11.Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)											
S.No.	Name (Brand/Generic)			Dose used	Route used	Frequency (OD,BD,etc)	Therapy dates Indication		Indications		
							Date Started	Date Stopped			
i											
ii											
iii *											
Additional Information:						D. REPORTER DETAILS					
						16.Name and Professional Address:_____					
						Pin: _____				E-mail: _____	
						Tel. No. (with STD code) _____					
						Occupation: _____				Signature: _____	
						17.Date of the report (dd/mm/yyyy): _____					
						Sign and Name of Receiver- _____					
Confidentiality: The patients identity is held in strict confidence and protected to the fullest extent. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction. Submission of an ADR report does not have any legal implication on the reporter.											