

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

ected Advition start	2. Age at time of evor Date of	he 3 vent birth: 4	. Sex: M □ F[. Body-We	eight:	12. Relev	ant tests	/ laborato	ry data with d	ates	
ected Advition start	time of evor Date of	vent birth:	M □ F	eight:	12. Relev	ant tests	/ laborato	ry data with d	ates	
ected Advition start	time of evor Date of	vent birth:	M □ F	eight:	12. Relev	ant tests	/ laborato	ry data with d	ates	
ected Adv tion start	time of evor Date of	vent birth:	M □ F	eight:						
ected Adv tion start of recover	or Date of verse React	birth: 4	. Body-We	eight:						
ected Adv tion start of recover	verse React	4.	. Body-We	eight:						
tion start of recover		_	•							
tion start of recover		_	•							
tion start of recover		_	K	7						
tion start of recover				,						
of recover	ed on Date:						•	ding preexisting	_	
		1			conditions (e.g. allergies, race, pregnancy, smoking, alcoho					
	<u>y:</u> :ion or prob	lem ·			use, hepa	tic/renal d	lysfunction,	etc:		
ibe react	lon or proc	nem.			If the nat	iont is a f	famala wh	ether pregna	nt2	
					If the patient is a female, whether pregnant?					
					res □ /	NO L	Yes,			
					Date of last menstrual period:					
					Expected date of delivery:					
					14. Serio	usness of	the reacti	on		
					☐ Death	(dd/mm/y	ууу) 🗆	☐ Congenital	anomaly	
					☐ Life - threatening ☐ Persistent or significa Hospitalization -initial disability or incapacit or prolonged					
					Other (specify):					
						mes	¬			
						L uing F		_	r (specify)	
ected Me	dication (s)				Contin	anig [_ Necovered		r (Specify)	
Name	Manufa-		Ехр.	Dos	e Route	Frequer	ncv Theran	v dates (if	Reason f	
rand and			Date		. '''	'	,			
r generic	,	Lot No.	(if					Date	prescribe	
me)	,	(if known)	known)					stopped	for	
•		,								
									 	
	Name rand and or generic me)	Name Manufa- rand and cturer (if known) me) known	rand and cturer (if known) Lot No. (if known) aken with suspected drug	Name Manufa- Batch Exp. rand and cturer (if No. / Date or generic known) Lot No. (if me) (if known) known) aken with suspected drug	Name Manufa- Batch Exp. Dos rand and cturer (if No. / Date used or generic known) Lot No. (if (if known) known)	Date of la Expected 14. Serion Death Life Hospit or pro Requir impair Other (15. Outco Fatal Contine ected Medication (s) Name Manufa- rand and cturer (if No. / Date used or generic known) Lot No. (if known) which is a serion of la cturer (if known) lot No. (if known) which is a serion of la Exp. Dose used used used aken with suspected drug	Date of last mensi Expected date on 14. Seriousness of Death (dd/mm/y) Life - threateni Hospitalization - or prolonged Required interve impairment / da Other (specify): 15. Outcomes Fatal Continuing ected Medication (s) Name Manufa- Batch Exp. Dose Route rand and cturer (if No. / Date used or generic known) Lot No. (if (if known) known) aken with suspected drug	Expected date of delivery 14. Seriousness of the reacti Death (dd/mm/yyyy) Life - threatening Hospitalization -initial or prolonged Required intervention to pre impairment / damage Other (specify): 15. Outcomes Fatal Recoverin Continuing Recovered ected Medication (s) Name Manufa- rand and cturer (if No. / Date rand and cturer (if No. / Date or generic known) Lot No. (if me) Green With suspected drug	Date of last menstrual period: Expected date of delivery: 14. Seriousness of the reaction Death (dd/mm/yyyy) Congenital and disability or it or prolonged Required intervention to prevent permanent impairment / damage Other (specify): 15. Outcomes Fatal Recovering Unkn Continuing Recovered Othe continuing Recovered Other (specify): 15. Outcomes Fatal Recovering Unkn Continuing Recovered Other (specify): 15. Outcomes Fatal Recovering Unkn Continuing Recovered Other (specify): Date Started Stopped	

Sr. No.	9. Reaction abated after drug stopped or dose reduced						10. Reaction reappeared after reintroduction:					
as Per C	Yes	No	Unknown	NA	Reduced dose		Yes	No	ı: Unknowr	NA	If reintroduce d, dose	
i. ii.												
iii. iv.												
11. Concomitant medical product including self medication and herbal remedies with therapy dates (excluding those used to treat reaction):					D. Reporter 16. Name and professional address:							
					PIN Code : E-mail: Tel. No. (with STD code):							
					OccupationSignature							
						17. Causa	ality Asses	smer		3. Date eport	e of this	

NOTE: PLEASE DO NOT LEAVE ANY FIELD BLANK. STRIKE OUT WHERE INFORMATION IS 'NOT AVAILABLE' OR 'NOT APPLICABLE'

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. The pharmacovigilance staff at INTAS is not expected to and will not disclose the reporter's identity in response to a request from the public. **Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.**

Note: Fill-up the print copy of the form as completely as possible and send by post to the following

Address: PV Cell, Medical Services Dept., INTAS Pharmaceuticals Limited, Corporate House, Opposite Sola Bridge, Off S. G. Highway, Thaltej, Ahmedabad – 380 054. Gujarat. India.