## Form: Collection of ADR information.

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ADVERSE EVENT REPORT Page 1 of 2													
PATIENT INFORMATION:													
Patient initials:								Date:					
COUNTRY:													
REPORT T	VDE.	☐ Init	ial [	Follow-	un								
DATE OF	AG		RACE	SEX			HEIG	НТ	WEIGHT	ONSE	ET 1	RECOVERY	
BIRTH DD/MM/YYY	v									DATI		DATE DD/MM/YYYY	
DD/WIWI/ 1 1 1	1				Male					DD/WII	VI/ I I I I	OD/IVIIVI/ I I I I	
					Female								
ADVERSE	EVENT	INFORM	MATION	N:				J					
ADVERSE	EVENT(	S) IN ME	EDICAL '	TERMS (	diagnosis	s, if poss	sible)		Seriousnes				
								C	Check all appropriate to event				
Description	of event:							<u>'</u> [	Patient	died			
											onged inpati	onged inpatient	
									hospitalization  Involved persistent or significant disability				
									or incapacity				
									Life-threatening				
									☐ Congenital anomaly/birth defect☐ Other significant medical events				
								L	_] Other s	ignificant	medical eve	nts	
HISTORY :								TEST / LABORATORY FINDINGS (enter only those findings					
PATIENT'S							necessary for AE diagnosis or course description)						
existing experience		conditions	s such as	disease, al	llergies, s	similar							
Схренен	ccsj												
SUSPECT	DRUG I	NFORM	ATION	:	ı	,		1	ı				
Produc								Freque	1 3			Indication	
Brand	Gener	rer		number	date		use			om )	(To)		
name	Name					-			DD/	MM/YYYY	DD/MM/YYY	Y	

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CONCOMITA	NT DRUGS								
DRUG NAME(S)		DOSE	THERAI		Y DATES	REASON FOR USE			
			(from )		(To)				
Brand name	Generic Name		DD/MM/YYY	ΥY	DD/MM/YYYY				
name	Tvanic								
		JSPECT DRUG (1		• •	e)				
☐ No Action	Taken		Withdraw	'n	☐ Treatment taken				
Did Danatian D	): A 64-	Stanain a of D	-0	D: 1 D -	i D 1 A &	han Bastantina of Duras			
Yes		or Stopping of Dru ot Applicable		Yes	= =	fter Restarting of Drug?  Not Applicable  Unknown			
	110 🗀 11	ot Applicable	Unknown   res   No			Thot Applicable			
OUTCOME O	F THE PATIE	ENT/AE							
	_		PP 3 0 ( 3 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1						
	y Recovered	Date of recovery:	DD/MM/YYYY		Condition still pr	present and unchanged			
Recovered	with sequelae	•			Condition deterior	orated			
Condition i	improving				☐ Death Autopsy: ☐ No ☐ Yes				
ASSESSMENT	Γ OF CAUSA	LITY							
Probab	le	Possible		☐ No	Not Related Unknown				
REPORTER'S	S INFORMA	TION:							
NAME, ADDR	RESS, TELEP	HONE NUMBER	AND EMAI	L OF	DATE OF THIS REPORT				
REPORTE	R				DD/MM/YYYY				
					☐ HCP ☐ CONSUMER ☐ OTHER				
						NSUMER   OTHER			
					Signature: Senders Contact details:				
					Macleods Pharmaceuticals Limited				
					Bldg No 95,				
					Opp Suncity Hotel, Maheshwari Nagar,				
					MIDC, Andheri (East),				
					Mumbai - 400093, INDIA				
					Email ID: safety@macleodspharma.com India Toll Free: 1-800-267-1222				