

TITLE	WOCKHARDT ADR COLLECTION FORM (SUSPECTED ADVERSE DRUG REACTION REPORTING FORM FOR VOLUNTARY REPORTING OF ADVERSE DRUG REACTIONS BY HEALTHCARE PROFESSIONAL)
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Wockhardt Corporate Office, Wockhardt Limited, Wockhardt Towers, Bandra Kurla Complex, Bandra (East), Mumbai-400051, India. PV Safety Toll-free No. 18002588127, 022-71596770 Email: pvsafety@wockhardt.com	11. Wockhardt Reference No: (To be filled by Wockhardt only)								
A. Patient Information	12. Relevant tests / laboratory data with dates								
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%; padding: 5px;">1. Patient Initials</td> <td style="width: 20%; padding: 5px;">2. Age at time of Event or date of birth</td> <td style="width: 20%; padding: 5px;">3. Sex M ☐ F ☐</td> </tr> <tr> <td colspan="3" style="padding: 5px;">4. Weight</td> </tr> </table>	1. Patient Initials	2. Age at time of Event or date of birth	3. Sex M ☐ F ☐	4. Weight			13. Other relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc)		
1. Patient Initials	2. Age at time of Event or date of birth	3. Sex M ☐ F ☐							
4. Weight									
B. Suspected adverse reaction									
5. Date of reaction started:									
6. Date of recovery:									
7. Describe reaction or problem:	14. Whether the reaction is Serious - Yes ☐ No ☐ (Please Tick) <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; padding: 5px;">Death(dd/mm/yyyy) ☐</td> <td style="width: 50%; padding: 5px;">Congenital anomaly ☐</td> </tr> <tr> <td style="padding: 5px;">Life threatening ☐</td> <td style="padding: 5px;">Required intervention to prevent permanent impairment / damage ☐</td> </tr> <tr> <td style="padding: 5px;">Hospitalization-initial or prolonged ☐</td> <td style="padding: 5px;">Other (specify) ☐</td> </tr> <tr> <td style="padding: 5px;">Disability ☐</td> <td></td> </tr> </table>	Death(dd/mm/yyyy) ☐	Congenital anomaly ☐	Life threatening ☐	Required intervention to prevent permanent impairment / damage ☐	Hospitalization-initial or prolonged ☐	Other (specify) ☐	Disability ☐	
Death(dd/mm/yyyy) ☐	Congenital anomaly ☐								
Life threatening ☐	Required intervention to prevent permanent impairment / damage ☐								
Hospitalization-initial or prolonged ☐	Other (specify) ☐								
Disability ☐									
15. Outcomes (Please tick relevant box) <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%; padding: 5px;">☐ Fatal</td> <td style="width: 33%; padding: 5px;">☐ Recovering</td> <td style="width: 33%; padding: 5px;">☐ Unknown</td> </tr> <tr> <td style="padding: 5px;">☐ Continuing</td> <td style="padding: 5px;">☐ Recovered</td> <td style="padding: 5px;">☐ Other (Specify) _____</td> </tr> </table>		☐ Fatal	☐ Recovering	☐ Unknown	☐ Continuing	☐ Recovered	☐ Other (Specify) _____		
☐ Fatal	☐ Recovering	☐ Unknown							
☐ Continuing	☐ Recovered	☐ Other (Specify) _____							

C. Suspected medication(s):

Sl. No	8. Name (brand and /or generic name)	Manufacturer (if known)	Batch No./ Lot No. (if known)	Expiry. Date (if known)	Dose used	Route used	Frequency	Therapy dates (if known give duration)		Indication (S)
								Date started	Date stopped	
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

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Concomitant Medication(s):		D. 16 Reporter details	
		Name	
		Address	
		Tel. No.	
		E-mail id	
		Occupation	
		Signature	
		Consent to follow up	
17. Causality Assessment	18. Date of this report (dd/mm/yyyy)		