



SUSPECTED ADVERSE DRUG REACTION REPORTING FORM (FOR DRUGS USED IN PROPHYLAXIS/TREATMENT OF COVID-19)

For **VOLUNTARY** reporting of ADRs by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION (National Coordination Centre-Pharmacovigilance Programme of India)
Ministry of Health & Family Welfare, Government of India, Sector-23, Raj Nagar, Ghaziabad-201002
PvPI Helpline (Toll Free) : 1800-180-3024 (9:00 AM to 5:30 PM, Monday-Friday)

A. PATIENT/SUBJECT INFORMATION																													
Patient/Subject Category : a. Lab confirmed COVID-19 case <input type="checkbox"/> b. Asymptomatic Healthcare Worker involved in the care of suspected or confirmed COVID-19 cases <input type="checkbox"/> c. Asymptomatic household contacts of laboratory confirmed cases <input type="checkbox"/> d. Others (Please specify)			Reg. No./IPD No./OPD No./CR No. : AMC Report No. : Worldwide Unique No. : To be generated by PvPI																										
1. Patient/Subject initials 2. Age/Date of Birth 3. Weight (in Kg)			9. Relevant tests/laboratory data with dates Test for COVID-19 : RT PCR Test <input type="checkbox"/> Rapid Antibody Test <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Not done <input type="checkbox"/>																										
4. Gender : Male <input type="checkbox"/> Female <input type="checkbox"/> Transgender <input type="checkbox"/>		5. If female pregnant Yes <input type="checkbox"/> No <input type="checkbox"/>	6. Lactating Yes <input type="checkbox"/> No <input type="checkbox"/>	10. Any other tests performed : 1. Chest X-Ray Yes <input type="checkbox"/> No <input type="checkbox"/> 2. ECG Findings, if any Yes <input type="checkbox"/> No <input type="checkbox"/> 3. Biochemical Examination such as Serum Electrolytes (Na, K, Mg, Ca etc.) Yes <input type="checkbox"/> No <input type="checkbox"/> 4. Ophthalmology Exam findings, if any Yes <input type="checkbox"/> No <input type="checkbox"/> 5. Radiological examination Yes <input type="checkbox"/> No <input type="checkbox"/> 6. Other Relevant information, if any																									
B. SUSPECTED ADVERSE REACTION																													
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 5%;">S.No.</th> <th style="width: 20%;">Reaction</th> <th style="width: 10%;">Start Date</th> <th style="width: 10%;">End Date</th> <th style="width: 55%;">Outcome*</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td></tr> </tbody> </table>					S.No.	Reaction	Start Date	End Date	Outcome*																				
S.No.	Reaction	Start Date	End Date	Outcome*																									
* Outcome may be indicated as (✓) one of the following (a) Recovered (b) Not Recovered (c) Recovered with sequelae (d) Recovering (e) Fatal (f) Unknown																													
7. Describe Event(s)/Reaction(s) with treatment details, if any in chronological order			11. Recent Travel Information : Recent History of International Travel : Yes <input type="checkbox"/> No <input type="checkbox"/> Country Visited : Date of Return to India : Inter-state travel/domestic travel																										
8. Seriousness of the reaction : No <input type="checkbox"/> if Yes <input type="checkbox"/> (please tick appropriate box) Death (dd/mm/yyyy) <input type="checkbox"/> Life threatening <input type="checkbox"/> Hospitalization/Prolongation of hospitalization <input type="checkbox"/> Other Medically important events <input type="checkbox"/>			12. Relevant medical/medication history : Allergy/Hypersensitivity Reaction <input type="checkbox"/> Chronic Alcoholism <input type="checkbox"/> Smoking <input type="checkbox"/> Obesity <input type="checkbox"/> Renal Dysfunction <input type="checkbox"/> Hepatic Dysfunction <input type="checkbox"/> Diabetes <input type="checkbox"/> Epilepsy/Seizures <input type="checkbox"/> Bronchial Asthma <input type="checkbox"/> Cardiovascular Disease <input type="checkbox"/> Chronic Lung Disease <input type="checkbox"/> Immunodeficiency Disorder <input type="checkbox"/> Immunosuppressant Drug <input type="checkbox"/> Anaemia <input type="checkbox"/> Neurological disorder <input type="checkbox"/> G-6-PD Deficiency <input type="checkbox"/> Dermatological findings, if any <input type="checkbox"/> Others <input type="checkbox"/>																										
13. Drug Interaction : Mention name of any interacting (with Suspected Drug) drug taken :																													

C. SUSPECTED MEDICINE(S)

S. No.	Drug Name (Brand/Generic)	Manufacturer/ MAH# (if known)	Batch No./Lot No.	Exp. Date (if known)	Dosage Form	Dose used	Route of Admn.	Frequency (Once a day, Twice a day etc.)	Therapy Dates		Indication	Casualty Assessment (Prefer WHO-UMC Scale)
									Date started	Date stopped		
i.												
ii.												
iii.												
iv.												

S.No.	Drug Name	Reaction abated on (please tick)				Reaction if reappeared after drug reintroduction			
		Drug withdrawal	Dose reduction	Without modification of dose	Any other	Yes	No	Effect unknown	Dose (if reintroduced)
i.									
ii.									
iii.									

14. Concomitant medication including drug used for co-morbidities, and complementary medicines with therapy dates (Exclude those used to treat reaction)

S.No.	Name (Brand/Generic)	Dose used	Route used	Frequency (Once a day, twice a day etc.)	Therapy Dates		Indication
					Date started	Date stopped	
i.							
ii.							
iii.							
iv.							

D. REPORTER DETAILS

15. Name of the Healthcare Professional with Address : _____

 Pin : _____ E-mail : _____ Tel. No. (with STD code) : _____
 Occupation : _____ Signature : _____

16. Date of this report (dd/mm/yyyy) :

Sign. and Name of Receiver -

Confidentiality : The patient's 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.

* Use separate page for more information, #MAH-Marketing Authorization Holder

ADVICE ABOUT REPORTING**A. What to report?****All adverse events should be reported**

Report every serious adverse drug reactions. A reaction is serious when the patient outcome is :

- Death
- Life-threatening
- Hospitalization (initial or prolonged)

Report all non-serious, known or unknown, frequent or rare adverse drug reactions.

B. Who can report?

All healthcare professionals (Clinicians, Dentists, Pharmacists and Nurse etc.) can report adverse drug reactions

C. Where to report?

Duty filled in Suspected Adverse Drug Reaction Reporting Form can be sent to the nearest Adverse Drug Reaction Monitoring Centre (AMC) or directly to the National Coordination Centre (NCC) for PvPI.

Call on Helpline (Toll Free) 1800 180 3024 to report ADRs or directly mail this filled form to pvpi.ipc@gov.in

A list of nationwide AMCs is available at : <http://www.ipc.gov.in>, http://www.ipc.gov.in/PvPI/pv_home.html

D. What happens to the submitted information?

Information provided in this form is handled in strict confidence. The causality assessment is carried out at AMCs by using WHO-UMC scale. The analyzed forms are forwarded to the NCC-PvPI through ADR database. Finally the data is analyzed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Centre in Sweden.

The reports are periodically reviewed by the NCC-PvPI. The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.

The Signal Review Panel of PvPI reviews the data and suggests any interventions that may be required.

E. Mandatory fields for suspected ADR Reporting Form

Patient initials, age at onset of reaction, reaction term(s), date of onset of reaction, suspected medication(s) & reporter information.

For Adverse Drug Reaction Reporting Tools

- E-mail : pvpi.ipc@gov.in
- PvPI Helpline (Toll Free) : 1800 180 3024 (9:00 AM to 5:30 PM, Monday-Friday)
- ADR Mobile App : "ADRPvPI"