Medicines Control Authority of Zimbabwe

PVF 17

PHARMACOVIGILANCE AND CLINICAL TRIALS DIVISION

MEDICINE SAFETY AND EFFICACY MONITORING FORM FOR COVID-19 PROPHYLAXIS

This form should be completed for medicines obtained under Section 75 of the Medicines and Allied Substances Control Act [Chapter 15:03] to assess the medicine's treatment outcomes and safety in the prophylaxis of COVID-19 disease, or any other medicines deemed necessary by the Authority. Identities of reporter, patient and institute will remain CONFIDENTIAL. This form is to be completed for EACH patient who is prescribed/or dispensed a medicine for prophylaxis of COVID-19 disease. Adverse Drug Reactions experienced by the patient should be submitted electronically on https://e-pv.mcaz.co.zw or by completing hard copy ADR form attached.

SECTION A

Patient details

Patient Initials:	Date of Birth/Age: ……...
Weight if known: Height *if known*:	Gender: ☐ Male ☐ Female

SECTION B

Risk and exposure assessment

Risk of getting COVID-19	☐ High ☐ Medium ☐ Low Briefly Justify risk category: ……
Exposure to COVID-19	☐ Exposed ☐ Unexposed ☐ Unknown Briefly Explain setting of exposure: ……
Comorbid conditions	☐ Asthma ☐ Diabetes Mellitus ☐ Cardiovascular disease ☐ Malignancy ☐ Chronic lung disease ☐ Pregnancy ☐ Unknown ☐ Hypertension ☐ HIV ☐ None ☐ Other: ……

SECTION C
Details of Medicine (s) Provided

Generic name	Brand name	Batch number	Dose	Route and frequency		Date started	Date stopped

Concomitant (other) medicines taken, including herbal medicines

Brand name	Batch number	Dose	Route and frequency		Indication	Date started	Date stopped

SECTION D
Outcome measures

Was the medicine effective	☐ Yes ☐ No
Did the patient develop any COVID-19 symptoms	☐ Yes ☐ No
If Yes, state the date and symptoms	Date of observation: ……/……./ …… ☐ Fever ☐ Body ache ☐ Shortness of breath ☐ Diarrhoea ☐ Tiredness ☐ Headache ☐ Nasal congestion ☐ Sore throat ☐ Cough ☐ Runny nose ☐ Loss of smell ☐ None ☐ Other: ……
Did the patient test positive for COVID-19	☐ Yes ☐ No
If yes, state the date and type of test done	☐ PCR test ☐ Antibody test

SECTION E
Safety evaluation: Adverse events/Side effects

Did the patient experience any side effects/adverse events while taking this medicine? ☐ Yes ☐ No

If yes proceed to complete the attached ADR reporting form, alternatively adverse drug reactions experienced by the patient may be submitted electronically on https://e-pv.mcaz.co.zw

Reporter details

Forename(s): …….. Surname: …….....

Institution: ……...

Designation: ……

Email: ……. Mobile/Telephone number: ……...