

#### COMPOSITION

Each capsule contains Molnupiravir INN 200 mg.

### **PHARMACOLOGY**

Molnupiravir is an antiviral drug. It is a prodrug that is metabolised to the ribonucleoside analogue N-hydroxycytidine (NHC). After distributing into cells, it is phosphorylated to form the pharmacologically active ribonucleoside triphosphate (NHC-TP). NHC-TP incorporation into viral RNA by the viral RNA polymerase, results inhibition of viral replication.

### **INDICATION**

As Emergency Use Authorization (EUA), it is indicated for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults with a positive SARS-CoV-2 diagnostic test and who have at least one risk factor for developing severe illness.

### **DOSAGE & ADMINISTRATION**

The recommended dose for adult is 800 mg (four 200 mg capsules) taken every 12 hours for 5 days. The safety and efficacy of it when administered for periods longer than 5 days have not been established.

No dosage adjustment is required for elderly or renal / hepatic impaired patients.

If the patient misses a dose within 10 hours of the time it is usually taken, missed dose should be taken within 10 hours from the scheduled dosing time.

If the missed dose is over than 10 hours of the time it is usually taken, it should not take the missed dose and instead take the next dose at the regularly scheduled time. The patient should not double the dose to make up for a missed dose.

It is taken orally with or without food. It should be swallowed whole with a sufficient amount of fluid (e.g., a glass of water). It should not be opened, crushed or chewed.

#### CONTRAINDICATION

It is contraindicated in patients with hypersensitivity to the active substance or to any of the excipients of the product.

## **WARNING & PRECAUTION**

No study on the effects on the ability to drive and use of machines have been performed.

# SIDE EFFECTS

The most common side effects reported during treatment and during 14 days after the last dose were diarrhoea, nausea, dizziness and headache.

# **USE IN PREGNANCY & LACTATION**

There are no data from the use of Molnupiravir in pregnant women. Studies in animals have shown reproductive toxicity. It is unknown whether Molnupiravir or any of the components of it are present in human milk, affect human milk production, or have effect on the breastfed infant. Based on the potential for adverse reactions on the infant, breast-feeding is not recommended during treatment and for 4 days after the last dose of it.

### **USE IN CHILDREN**

The safety and efficacy in patients below 18 years of age have not been established.

### **DRUG INTERACTION**

No drug interactions have been identified based on the available data.

### **OVERDOSAGE**

There is no human experience of overdosage with Molnupiravir. Treatment of overdose should consist of general supportive measures including the monitoring of the clinical status of the patient.

# **STORAGE CONDITION**

Store below  $30^{\circ}\text{C}$  temperature in a dry place. Protect from light & moisture. Keep out of the reach of children.

## **HOW SUPPLIED**

Each box contains 8 capsules in Alu-Alu blister pack.



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