# Insert
# Ezavir 200 mg Capsule

90 mm

210 mm

## Ezavir
Molnupiravir Capsule

**Description**
Ezavir is a preparation of Molnupiravir which is a prodrug that is metabolised to the ribonucleoside analogue N-hydroxycytidine (NHC) which distributes into cells where it is phosphorylated to form the pharmacologically active ribonucleoside triphosphate (NHC-TP). NHC-TP acts by a mechanism known as viral error catastrophe. NHC-TP incorporation into viral RNA by the viral RNA polymerase, results in an accumulation of errors in the viral genome leading to inhibition of replication.

**Antiviral Activity**
NHC was active in cell culture assays against SARS-CoV-2 with 50% effective concentrations (ECSO) ranging between 0.67 to 2.66 //M in A-549 cells and 0.32 to 2.03 PM in Vero E6 cells. NHC had similar activity against SARS-CoV-2 variants B.1.1.7 (Alpha), B.1351 (Beta), P.1 (Gamma), and B.1.617.2 (Delta) with EC50 values of 1.59, 1.77 and 1.32 and 1.68 PM, respectively. No impact was observed on the in vitro antiviral activity of NHC against SARS-CoV-2 when NHC was tested in combination with abacavir, emtricitabine, lamivudine, nelfinavir, remdesivir, ribavirin, sofosbuvir, tenofovir or hydroxychloroquine.

**Indications**
Ezavir is indicated for 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 and Administrations**
The recommended dose of Ezavir is 800 mg (four 200 mg capsules) taken orally every 12 hours for 5 days. The safety and efficacy of Molnupiravir when administered for periods longer than 5 days have not been established. Ezavir 200 mg capsules can be taken with or without food. The capsules should be swallowed whole with a sufficient amount of fluid (e.g., a glass of water). The capsules should not be opened, crushed or chewed. Ezavir should be administered as soon as possible after a diagnosis of COVID-19 has been made.

**Missed Dose**
If the patient misses a dose of Ezavir within 10 hours of the time it is usually taken, the patient should take as soon as possible and resume the normal dosing schedule. If a patient misses a dose by more than 10 hours, the patient 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.

**Contraindications**
Hypersensitivity to the active substance or to any of the excipients.

**Warning and Precautions**
No data available.

**Side Effects**
Most commonly reported side effects after administering Molnupiravir are nausea, headache and diarrhoea.

**Use in Specific Populations**
**Pregnancy**
There are no data from the use of Ezavir in pregnant women. Studies in animals have shown reproductive toxicity. Ezavir is not recommended during pregnancy. Women of childbearing potential should use effective contraception for the duration of treatment and for 4 days after the last dose of Ezavir (Molnupiravir).

**Breast-feeding**
It is unknown whether Molnupiravir or any of the components of Molnupiravir are present in human milk, affect human milk production, or have effect on the breastfed infant. Animal lactation studies with Molnupiravir have not been conducted.

Based on the potential for adverse reactions on the infant from Ezavir, breast-feeding is not recommended during treatment and for 4 days after the last dose of Ezavir.

**Fertility**
There were no effects on female or male fertility in rats at NHC exposures approximately 2 and 6 times respectively, the exposure in humans at the recommended human dose (RHD).

**Elderly**
No dose adjustment is required based on age.

**Renal Impairment**
No dose adjustment is required for patients with renal impairment.

**Hepatic Impairment**
No dose adjustment is required for patients with hepatic impairment.

**Paediatric population**
The safety and efficacy of Molnupiravir in patients below 18 years of age have not been established. No data are available.

**Drug Interactions**
No drug interactions have been identified based on the limited available data. No clinical interaction studies have been performed with Molnupiravir. Molnupiravir is hydrolysed to n-hydroxycytidine (NHC) prior to reaching systemic circulation. Uptake of NHC and metabolism to NHC-TP are mediated by the same pathways involved in endogenous pyrimidine metabolism. NHC is not a substrate of major drug metabolising enzymes or transporters. Based on in vitro studies, neither Molnupiravir nor NHC are inhibitors or inducers of major drug metabolising enzymes or inhibitors of major drug transporters. Therefore, the potential for Molnupiravir or NHC to interact with concomitant medications is considered unlikely.

**Overdose**
There is no human experience of overdosage with Ezavir. Treatment of overdose with Ezavir should consist of general supportive measures including the monitoring of the clinical status of the patient. Haemodialysis is not expected to result in effective elimination of NHC.

**Pharmaceutical Precautions**
Store below 30°C. Keep out of the sight & reach of children.
Protect from moisture & light.

**Packing**
**Ezavir Capsule:** Each HDPE container contains 40 capsules and one packet silica gel in a sealed plastic container.

Manufactured by :
GENERAL Pharmaceuticals Ltd.
Mouchak, Kaliakair, Gazipur, Bangladesh

22066382-V00

*The information given here is limited. For further information consult your doctor or pharmacist.*

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