Composition: Each Capsule Contains Molnupiravir INN 200mg.

Pharmacology: Mechanism of Action: Molnupiravir is a prodrug that is metabolised to the ribonucleoside analogue Nhydroxycytidine (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.

Absorption: Following twice daily oral administration of 800 mg Molnupiravir, the median time to peak plasma NHC concentrations (Tmax) was 1.5 hours. Effect of Food on Oral Absorption:In healthy subjects, the administration of a single 200 mg dose of Molnupiravir with a high-fat meal resulted in a 35% reduction in NHC peak concentrations (Cmax), AUC was not significantly affected.

Distribution: NHC does not bind to plasma proteins.

Elimination: The effective half-life of NHC is approximately 3.3 hours. The fraction of dose excreted as NHC in the urine was ≤3% in healthy participants.

Other special populations:

Gender, Race, Age: Population pharmacokinetic analysis showed that age, gender, race and ethnicity do not meaningfully influence the pharmacokinetics of NHC.

Indications: 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: Adults: The recommended dose of Molnupiravir 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. Molnupiravir should be administered as soon as possible after a diagnosis of COVID-19 has been made and within 5 days of symptom onset.

Missed dose: If the patient misses a dose of Molnupiravir 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.

Special populations: Elderly: No dose adjustment of 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.

Method of administration: For oral use. Molnupiravir 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. Or, as directed by the registered physician.

Contraindications: It is contraindicated in patients with known hypersensitivity to active ingredient or any other components of this product.

Precautions: This medicinal product contains less than 1 mmol sodium (23mg) per dose of 4 capsules, that is to say essentially 'sodium-free'.

Side effects: In an interim analysis of a Phase 3 trial of subjects with mild to moderate COVID-19 treated with Molnupiravir the most common adverse reactions (≥1% of subjects) reported during treatment and during 14 days after the last dose were diarrhoea (3%), nausea (2%), dizziness (1%) and headache (1%) all of which were Grade 1 (mild) or Grade 2 (moderate).

Use in pregnancy & lactation: Pregnancy: There are no data from the use of Molnupiravir in pregnant women. Studies in animals have shown reproductive toxicity. Molnupiravir 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 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 Molnupiravir, breast-feeding is not recommended during treatment and for 4 days after the last dose of Molnupiravir.

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).

Use in Child: 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 Molnupiravir. Treatment of overdose with Molnupiravir 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.

Storage: Store below 30° C in a dry place.

Packaging: Each box contains 40's capsules in container.