

FACT Sheet on Molnupiravir for Patients

Q. What is Molnupiravir-200 Capsule?

- Molnupiravir (EIDD-2801/MK-4482), the pro drug of the active antiviral ribonucleoside analog β -D-N4-hydroxycytidine (NHC; EIDD-1931), which has activity against number of RNA viruses, including SARS-CoV-2 that causes COVID-19.

Q. Is it safe to use Molnupiravir-200 Capsule in COVID-19?

- Molnupiravir (Molnupiravir) offers a favourable tolerability and safety profile. The most frequent adverse events (reported in $\geq 1\%$ of subjects) reported during treatment were diarrhoea, nausea, dizziness and headache all of which were Grade 1 (mild) or Grade 2 (moderate).

Q. Are there any specific cautions associated with the use of Molnupiravir 200 Capsule?

- Molnupiravir (Molnupiravir) usage is limited to non-pregnant adults only. No dosage adjustments are indicated in elderly, renal impairment, and hepatic impairment.
- The safety and efficacy of Molnupiravir (Molnupiravir) in patients below 18 year of age have not been established.

Q. What if I miss the dose of Molnupiravir?

- 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.

Q. What are the instructions for Pregnant and Lactating mothers regarding usage of Molnupiravir?

- **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 of 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.

Q. For how long I should take Molnupiravir and what is the dosage?

- 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.

Q. What are the indications for Molnupiravir Capsule?

- Molnupiravir is indicated for treatment of mild to moderate coronavirus disease (COVID-19) in adults with a positive SARS-COV-2 diagnostic test and who have at least one risk factor for developing severe illness.
- One or more pre-defined risk factors for disease progression in COVID-19 are –
 - Age ≤60 years
 - Diabetes
 - Obesity (BMI>30)
 - Chronic kidney disease
 - Serious heart conditions
 - Chronic obstructive pulmonary disease
 - Active cancer

Q Is Molnupiravir-200safe for individuals below the age of 18 years?

- Molnupiravir has not been studied in paediatric patients. The safety and efficacy of Molnupiravir in patients below 18 years of age have not been established.