

MONUVIR™

EMERGENCY USE ONLY

Molnupiravir INN Capsule

DESCRIPTION

Monuvir™ is a preparation of Molnupiravir. It is an antiviral drug which is orally active and is developed for the treatment of influenza. It is a prodrug of the synthetic nucleoside derivative N4-hydroxycytidine, and exerts its antiviral action through introduction of copying errors during viral RNA replication including SARS-CoV-2, the causative agent of COVID-19.

Molnupiravir is a shape-shifter, called a tautomer. It assumes two forms, one which closely resembles uracil and the other cytosine. Because it appears in these two different forms, once it is recopied, the replicating polymerase develops transition mutations, where a U nucleotide is converted to a C and a C to U. Copying RNA that contains Molnupiravir results in fatal flaws in the sequence, stopping replication, shortening infection, and limiting transmission. The difference between the structure of an authentic nucleotide and Molnupiravir is apparently too subtle to trigger removal by the exonuclease repair function of the viral polymerase, a function that has bedeviled these of many other nucleoside inhibitors.

INDICATIONS

Monuvir™ is an antiviral medicine used to treat mild to moderate COVID-19 (caused by SARS-CoV-2) in adults who are at risk for developing severe illness. **Monuvir™** may help people with COVID-19 stay out of the hospital and feel better. Emergency use authorized oral therapeutic for the treatment of COVID-19 in Non-hospitalized patients with mild or moderate disease.

GENERAL INFORMATION

Asymptomatic or pre-symptomatic Infection: Individuals who test positive for SARS-CoV-2 by virologic testing using a molecular diagnostic (e.g., polymerase chain reaction) or antigen test, but have no symptoms.

- **Mild illness:** Individuals who have any of the various signs and symptoms of COVID-19 (e.g., fever, cough, sore throat, malaise, headache, muscle pain) without shortness of breath, dyspnoea, or abnormal chest imaging.

- **Moderate illness:** Individuals who have evidence of lower respiratory disease by clinical assessment or imaging and a saturation of oxygen (SpO₂) ≥94% on room air at sea level.

- **Severe illness:** Individuals who have respiratory frequency >30 breaths per minute, SpO₂ <94% on room air at sea level, ratio of arterial partial pressure of oxygen to fraction of inspired oxygen (PaO₂/FiO₂) <300 mmHg, or lung infiltrates >50%.

- **Critical illness:** Individuals who have respiratory failure, septic shock, and/or multiple organ dysfunction.

DOSAGE AND ADMINISTRATION

The recommended dose of Monuvir is four 200 mg capsules, every 12 hours for 5 days.

CONTRAINDICATIONS

Molnupiravir is contraindicated in patients with known hypersensitivity to Molnupiravir.

PRECAUTION AND WARNING

There are limited clinical data available for Molnupiravir. Serious and unexpected adverse events may occur that have not been previously reported with Molnupiravir use.

USE IN PREGNANCY AND LACTATION

Animal studies with molnupiravir have shown harmful effects to the unborn animal. **Monuvir™** is not recommended in pregnancy. **Monuvir™** has not been studied in pregnancy and it is not known if **Monuvir™** will harm your baby while you are pregnant.

If you are pregnant, think you may be pregnant, or are planning to have a baby, ask your doctor for advice. If you can become pregnant, you should use effective birth control while you are taking **Monuvir™** and for 4 days after the last dose of **Monuvir™**.

If you are breast-feeding or are planning to breastfeed, tell your doctor before taking this medicine. Breast-feeding is not recommended during treatment and for 4 days after the last dose of **Monuvir™**. This is because it is not known if **Monuvir™** gets into breast milk and will be passed to the baby.

CHILDREN AND ADOLESCENTS

Do not give this medicine to children and adolescents aged less than 18 years. The use of **Monuvir™** in persons aged less than 18 years has not yet been studied.

PHARMACEUTICAL PRECAUTION

Store at or below 25 °C temperature. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Monuvir™ 200 Capsule:

Box containing 1 strip of 10 capsules. Each capsule contains Molnupiravir INN 200 mg.

SK+F

Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

TONGI, GAZIPUR, BANGLADESH

TM. TRADEMARK

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