

PROPOSED CLEAN PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PRODUCT NAME strength pharmaceutical form

MOLUMUS® 200 hard gelatin capsules

Molnupiravir 200 mg

Sugar free

Read all of this leaflet carefully before you start taking MOLUMUS® 200.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- MOLUMUS® 200 has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What MOLUMUS® 200 is and what it is used for.
2. What you need to know before you use MOLUMUS® 200.
3. How to use MOLUMUS® 200.
4. Possible side effects.
5. How to store MOLUMUS® 200.
6. Contents of the pack and other information.

1. What MOLUMUS® 200 is and what it is used for

MOLUMUS® 200 contains the active substance molnupiravir.

MOLUMUS® 200 is an antiviral medicine that works against the virus that causes coronavirus disease 2019 (COVID-19). It is used to treat mild to moderate COVID-19 in adults who do not currently need oxygen due to COVID-19 and are at risk for progressing to severe illness. Your healthcare provider has recommended or given you MOLUMUS® 200 for the treatment of COVID-19. MOLUMUS® 200 may help people with COVID-19 stay out of the hospital and feel better.

What is COVID-19?

- COVID-19 is caused by a virus called SARS CoV-2.
- You can get COVID-19 through contact with another person who has the virus.

COVID-19 illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, serious illness, including breathing problems, can happen and may cause some of your other medical conditions to become worse. Older people and people of all ages with severe, long lasting (chronic) medical conditions like heart disease, lung disease and diabetes, for example seem to be at higher risk of being hospitalized for COVID-19.

What are the Symptoms of COVID-19?

The symptoms of COVID-19 may include fever, cough, and shortness of breath.

2. What you need to know before you take MOLUMUS® 200

Do not take MOLUMUS® 200:

- If you are allergic to molnupiravir or any of the other ingredients of this MOLUMUS® 200 (listed in section 6).

What should I tell my doctor before and while taking MOLUMUS® 200:

Tell your healthcare provider about all of your medical conditions, including if you:

- are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed.
- have any allergies.
- have any serious illnesses.
- are taking any medicines (prescription, over-the-counter, vitamins, or herbal products)

Other medicines and MOLUMUS® 200

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Pregnancy, Breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Your doctor will advise you regarding the safety of **MOLUMUS® 200** during pregnancy.

MOLUMUS® 200 is not recommended in pregnancy. MOLUMUS® 200 has not been studied in pregnancy and it is not known if MOLUMUS® 200 will harm your baby while you are pregnant.

If you can become pregnant, you should use effective birth control while you are taking MOLUMUS® 200 and for 4 days after the last dose of MOLUMUS® 200.

Breastfeeding

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 MOLUMUS® 200.** This is because it is not known if MOLUMUS® 200 gets into breast milk and will be passed to the baby.

Driving and using machinery:

It is not always possible to predict to what extent MOLUMUS® 200 may interfere with the daily activities of a patient. Some patients have reported dizziness during treatment with LAGEVRIO™. If you experience this effect, do not drive or use machines until the effect wears off (see Section 4, possible side effects).

MOLUMUS® 200 contains Sodium

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

3. How to take MOLUMUS® 200

Do not share medicines prescribed for you with any other person.

Always take MOLUMUS® 200 exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

You should start MOLUMUS® 200 within 5 days of the onset of COVID-19 symptoms.

How much to take:

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

How to take:

- Swallow the capsule whole with plenty of fluid (for instance a glass of water).
- Do not open, break, or crush the capsules. If you cannot swallow capsules whole, tell your healthcare provider.
- This medicine can be taken with or without food.

If you take more MOLUMUS® 200 than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take MOLUMUS® 200

- It is important that you do not miss or skip doses of this medicine.
- If you forget to take a dose within 10 hours of the time it is usually taken, you should take it as soon as possible and take the next one at the usual time.
- If you forget to take a dose by more than 10 hours, you should not take the missed dose and instead take the next one at the usual time.
- Do not take a double dose to make up for a missed dose.
- If you are not sure what to do, call your doctor or pharmacist.

If you stop taking using MOLUMUS® 200

Do not stop taking MOLUMUS® 200 without talking to your doctor first. This will give the medicine the best chance to keep you from becoming severely ill from COVID-19.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects:

MOLUMUS® 200 can cause side effects.

Not all side effects reported for MOLUMUS® 200 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MOLUMUS® 200, please consult your healthcare provider for advice.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Allergic reaction (hypersensitivity) – the sign may include wheezing, difficulty breathing
- Rashes or hives, itchiness, swelling.

These are all serious side effects. If you have them you may have had a serious reaction to MOLUMUS® 200. You may need urgent medical attention or hospitalisation.

The frequent side effects of MOLUMUS® 200 in adults are:

- diarrhoea.
- nausea.
- feeling dizzy.
- Headache

Less frequent side effects are:

- vomiting
- skin redness

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effect, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA publications: <http://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of MOLUMUS® 200.

5. How to store MOLUMUS® 200:**STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**

- Do not use after the expiry date stated on the label / carton.
- There are no special storage instructions for MOLUMUS® 200.
- Store in the original package below 25°C.
- Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).
- Return all unused medicine to your pharmacist.

6. Contents of the pack and other information**What MOLUMUS® 200 contains:**

The active substance is molnupiravir 200 mg.

The other ingredients are:

Capsule content: colloidal silicon dioxide (aerosil 200), crospovidone (polyplasdone XL-10), microcrystalline cellulose, (XLM90), povidone K-30 (kollidon 30), and sodium stearyl fumarate (PRUV).

Capsule shell content: gelatin and opacifier (i.e., Titanium Dioxide)

What MOLUMUS® 200 looks like and contents of the pack

MOLUMUS® 200 is size '2' (i.e., Cap (mm) = 6.37 ± 0.03 and body (mm) = 6.08 ± 0.03) hard gelatin white opaque color capsules, filled with white to off white color granular powder.

MOLUMUS® 200 hard gelatin capsules are packed in PVC/PVDC Alu pack of 10 Capsules.

Holder of Certificate of Registration:

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