

APPROVED PATIENT INFORMATION LEAFLET
Dr. Reddy's Laboratories (Pty) Ltd.
MOLNUPIRAVIR 200 DRL

SCHEDULING STATUS

S4

MOLNUPIRAVIR 200 DRL Capsules

Molnupiravir

Sugar free

Read all of this leaflet carefully before you start taking MOLNUPIRAVIR 200 DRL

- 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.
- MOLNUPIRAVIR 200 DRL 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 MOLNUPIRAVIR 200 DRL is and what it is used for
2. What you need to know before you take MOLNUPIRAVIR 200 DRL
3. How to take MOLNUPIRAVIR 200 DRL
4. Possible side effects
5. How to store MOLNUPIRAVIR 200 DRL
6. Contents of the pack and other information

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1. What MOLNUPIRAVIR 200 DRL is and what it is used for

MOLNUPIRAVIR 200 DRL contains the active substance molnupiravir.

MOLNUPIRAVIR 200 DRL 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.

MOLNUPIRAVIR 200 DRL 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 MOLNUPIRAVIR 200 DRL

Do not take MOLNUPIRAVIR 200 DRL:

- if you are allergic (hypersensitive) to molnupiravir or any of the other ingredients of

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MOLNUPIRAVIR 200 DRL (listed in section 6).

Warnings and precautions

Tell your healthcare provider about all our 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).

Children and adolescents

Do not give MOLNUPIRAVIR 200 DRL to children and adolescents aged less than 18 years.

The use of MOLNUPIRAVIR 200 DRL in persons aged less than 18 years has not yet been studied.

Other medicines and MOLNUPIRAVIR 200 DRL

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

MOLNUPIRAVIR 200 DRL with food and drink

MOLNUPIRAVIR 200 DRL may be taken with or without food.

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It is advised not to drink alcohol while you are taking MOLNUPIRAVIR 200 DRL.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking MOLNUPIRAVIR 200 DRL.

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

MOLNUPIRAVIR 200 DRL is not recommended in pregnancy.

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

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

Driving and using machines

It is not always possible to predict to what extent MOLNUPIRAVIR 200 DRL may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which MOLNUPIRAVIR 200 DRL affects them.

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Some patients have reported dizziness during treatment with MOLNUIRAVIR 200 DRL. If you experience this effect, do not drive or use machines until the effect wears off (see Section 4, Possible side effects).

3. How to take MOLNUIRAVIR 200 DRL

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

Always take MOLNUIRAVIR 200 DRL exactly as your doctor has told you. Check with your doctor if you are not sure.

Your doctor will determine what dose is appropriate for you.

You should start MOLNUIRAVIR 200 DRL within 5 days of the onset of COVID-19 symptoms.

How much to take:

The recommended dose 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.
- This medicine can be taken with or without food.

If you have the impression that the effect of MOLNUIRAVIR 200 DRL is too strong or too weak, tell your doctor or pharmacist.

If you take more MOLNUIRAVIR 200 DRL than you should

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If you take more MOLNUPIRAVIR 200 DRL than you should, contact your doctor or pharmacist straight away. If neither is available, contact the nearest hospital or poison centre.

If you forget to take MOLNUPIRAVIR 200 DRL

- 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.

Do not stop taking MOLNUPIRAVIR 200 DRL

Do not stop taking MOLNUPIRAVIR 200 DRL without talking to your doctor first.

4. Possible side effects

MOLNUPIRAVIR 200 DRL can have side effects.

Not all side effects reported for MOLNUPIRAVIR 200 DRL are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking MOLNUPIRAVIR 200 DRL, please consult your doctor, pharmacist or other healthcare professional for advice.

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If any of the following happens, stop taking MOLNUIRAVIR 200 DRL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- allergic reaction (hypersensitivity) – the signs may include wheezing, difficulty breathing, rashes or hives, itchiness, swelling. These are all very serious side effects.

If you have them, you may have had a serious reaction to MOLNUIRAVIR 200 DRL.

You may need urgent medical attention or hospitalisation.

The frequent side effects are:

- feeling dizzy
- headache
- loose or runny stools (diarrhoea)
- feeling sick (nausea)

The less frequent side effects are:

- throwing up (vomiting)
- swelling of the skin
- skin redness
- rash
- hives

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

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There may be side effects that are not listed here. Ask your healthcare provider for more information.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse.

You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications:

<https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of MOLNUPIRAVIR 200 DRL.

5. How to store MOLNUPIRAVIR 200 DRL

Store at or below 30 °C.

Store all medicines out of reach of children.

Do not use after the expiry date stated on the carton and blister labels.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What MOLNUPIRAVIR 200 DRL contains

Each capsule contains 200 mg of molnupiravir.

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The other ingredients are: croscarmellose sodium, hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose.

The hard gelatin capsule shell consists of: hydroxypropylmethylcellulose, purified water, titanium dioxide.

What MOLNUPIRAVIR 200 DRL looks like and contents of the pack

White to off white powder filled in white to off white opaque colored empty hypromellose capsules without imprinting.

The capsule shell size is '0'.

The dimension of the capsule is:

Body length: 18,10 mm to 18,90 mm

Cap length: 10,30 mm to 11,10 mm

Contents of the pack:

MOLNUPIRAVIR 200 DRL is packed in aluminum blisters containing 10,20,30,40, 50 and 60 capsules.

Not all pack sizes are marketed

7. Holder of Certificate of Registration

Dr. Reddy's Laboratories (Pty) Ltd.

Block B, 204 Rivonia Road

Morningside

Sandton

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2057

8. This leaflet was last revised in

25 July 2023

9. Registration number

56/20.2.8/1109

Access to the corresponding Professional Information

Detailed information on this medicine is available on the Dr. Reddy's Laboratories (Pty) Ltd. website: <http://www.drreddys.co.za>

For any information about this medicine, please contact the local representative of the Holder of Certificate of Registration:

Dr. Reddy's Laboratories (Pty) Ltd. Tel: +27 11 324 2100