

Applicant/PHCR: AUROGEN SA (PTY) LTD

Product proprietary name: MOLNARZ

Submitted: 17/05/2023

Dosage form and strength: Hard capsules, 200 mg

1.3.2 Patient Information Leaflet (APPROVED COPY)

PATIENT INFORMATION LEAFLET

S4

MOLNARZ , 200 mg (hard capsules)

Molnupiravir

Sugar free.

Read all of this leaflet carefully before you are given MOLNARZ.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- **MOLNARZ** 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 **MOLNARZ** is and what it is used for
2. What you need to know before you use **MOLNARZ**
3. How to use **MOLNARZ**
4. Possible side effects
5. How to store **MOLNARZ**
6. Contents of the pack and other information

Applicant/PHCR: AUROGEN SA (PTY) LTD

Product proprietary name: MOLNARZ

Submitted: 17/05/2023

Dosage form and strength: Hard capsules, 200 mg

1. What MOLNARZ is and what it is used for

MOLNARZ contains the active substance molnupiravir. **MOLNARZ** is an antiviral medicine used to treat mild to moderate COVID-19 (caused by SARS-CoV-2) in adults who are not on oxygen and not at risk for developing severe illness.

Your healthcare provider has recommended or given you **MOLNARZ** for the treatment of COVID-19. **MOLNARZ** may help people with COVID-19 stay out of the hospital and feel better.

2. What you need to know before you use MOLNARZ

Do not take MOLNARZ:

- if you are allergic to molnupiravir or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking molnupiravir.

Children and adolescents

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

Other medicines and MOLNARZ:

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

Applicant/PHCR: AUROGEN SA (PTY) LTD

Product proprietary name: MOLNARZ

Submitted: 17/05/2023

Dosage form and strength: Hard capsules, 200 mg

MOLNARZ should not interfere with other medicines that you may be taking. However, some medicines may affect how **MOLNARZ** works, or **MOLNARZ** may affect how your other medicines work.

Pregnancy, breastfeeding and fertility

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 MOLNARZ and for 4 days after the last dose of MOLNARZ.

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

If you are breastfeeding or are planning to breastfeed, tell your doctor before taking this medicine.

Breastfeeding is not recommended during treatment and for 4 days after the last dose of MOLNARZ. This is because it is not known if **MOLNARZ** gets into breast milk and will be passed to the baby.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed.

Applicant/PHCR: AUROGEN SA (PTY) LTD

Product proprietary name: MOLNARZ

Submitted: 17/05/2023

Dosage form and strength: Hard capsules, 200 mg

Some patients have reported dizziness, during treatment with **MOLNARZ**. if you experience this effect, do not drive or use machines until the effect wears off (see section 4, possible side effects).

MOLNARZ 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 MOLNARZ

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

You should start **MOLNARZ** within 5 days of the onset of COVID-19 symptoms.

How much to take

The recommended dose of **MOLNARZ** 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.

Your doctor will tell you how long your treatment with **MOLNARZ** will last. Do not stop any treatment unless your doctor tells you to do so.

If you have the impression that the effect of **MOLNARZ** is too strong or too weak, tell your doctor or pharmacist.

Applicant/PHCR: AUROGEN SA (PTY) LTD

Product proprietary name: MOLNARZ

Submitted: 17/05/2023

Dosage form and strength: Hard capsules, 200 mg

If you take more MOLNARZ than you should

If you take more **MOLNARZ** than you should, contact your doctor straight away.

If you forget to take MOLNARZ

- 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 MOLNARZ

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

4. Possible side effects

MOLNARZ can have side effects.

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

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

Applicant/PHCR: AUROGEN SA (PTY) LTD

Product proprietary name: MOLNARZ

Submitted: 17/05/2023

Dosage form and strength: Hard capsules, 200 mg

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Skin rash or itching.
- Fainting.
- Yellowing of your skin and eyes (also called jaundice).

These are all very serious side effects. If you have them, you may have had a serious reaction to **MOLNARZ**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you notice any of the following:

Frequent side effects:

- Diarrhoea
- Nausea
- Feeling dizzy
- Headache

These are all serious side effects. You may need urgent medical attention.

The below side effects occur less frequently:

- Vomiting
- Rash
- Hives

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

Applicant/PHCR: AUROGEN SA (PTY) LTD

Product proprietary name: MOLNARZ

Submitted: 17/05/2023

Dosage form and strength: Hard capsules, 200 mg

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 **MOLNARZ**.

5. How to store MOLNARZ

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 30 °C.

Protect from moisture.

Store in the original container. Keep tightly closed.

Keep the container in the outer carton.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

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 MOLNARZ contains

The active substance is molnupiravir. Each hard capsule contains 200 mg of molnupiravir.

The other ingredients are:

- Cellulose Microcrystalline PH101 Ph.Eur

Applicant/PHCR: AUROGEN SA (PTY) LTD

Product proprietary name: MOLNARZ

Submitted: 17/05/2023

Dosage form and strength: Hard capsules, 200 mg

- Croscarmellose Sodium Ph.Eur
- Hydroxypropyl cellulose Ph.Eur
- Magnesium stearate Ph.Eur

The capsule shell consists of the following:

- Hydroxy propylmethyl Cellulose EP
- Carrageenan EP
- Potassium Chloride USP/EP/NF
- Brilliant Blue FCF (E133)
- Iron oxide Yellow (E172)
- Titanium Dioxide Ph.Eur. (E171)

The capsule printing edible black ink consists of the following:

- Shellac (E904) Ph.Eur.
- Dehydrated Alcohol (E1510) Ph.Eur.
- Isopropyl alcohol Ph.Eur.
- Butyl Alcohol Ph.Eur.
- Propylene Glycol (E1520) Ph.Eur.
- Strong Ammonia Solution (E527) Ph.Eur.
- Potassium Hydroxide (E525) Ph.Eur.
- Purified water Ph.Eur.
- Black Iron oxide (E172) NF

Applicant/PHCR: AUROGEN SA (PTY) LTD

Product proprietary name: MOLNARZ

Submitted: 17/05/2023

Dosage form and strength: Hard capsules, 200 mg

What MOLNARZ looks like and contents of the pack

MOLNARZ:

White to off white granular powder filled in size '0' hard capsule with green opaque coloured cap and body imprinted with "MOL" on cap and '200' on body with BLACK TEK ink.

HDPE containers:

MOLNARZ 200 mg are also proposed to be packed in white opaque round HDPE containers closed with 38 mm white opaque polypropylene continuous thread (CT) closure with induction sealing wad. This HDPE container will be further packed in preprinted carton with package leaflet.

Pack size: 40's

HOLDER OF THE CERTIFICATE OF REGISTRATION

Aurogen SA (Pty) Ltd

Woodhill Office Park, Building 1, First Floor

53 Phillip Engelbrecht Avenue

Meyersdal, Ext. 12

1448, Johannesburg

South Africa

Registration number

57/20.2.8/0169

This leaflet was last revised in:

25 July 2023