

WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET

*This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.**

The medicine may be authorised for additional or different uses by national medicines regulatory authorities.

* https://extranet.who.int/pqweb/sites/default/files/documents/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[CV008 trade name][†]
Molnupiravir

*The warnings and instructions in this leaflet are intended for the person taking the medicine.
If you are a parent or carer responsible for giving the medicine to someone else such as a child,
you will need to apply the instructions accordingly.*

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have questions about the medicine, ask your health care provider.
- This medicine is for you only. Do not pass it on to others. It may harm them, even if their illness seems to be the same as yours..
- If you are concerned about any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [CV008 trade name] is and what it is used for
2. What you need to know before you take [CV008 trade name]
3. How to take [CV008 trade name]
4. Possible side effects
5. How to store [CV008 trade name]
6. Contents of the pack and other information

1. What [CV008 trade name] is and what it is used for

[CV008 trade name] contains the active substance molnupiravir. [CV008 trade name] is a medicine used to treat mild or moderate COVID-19 in adults who could go on to develop severe illness.

You should start taking [CV008 trade name] within 5 days of getting symptoms of the illness.

COVID-19 is a disease caused by a virus called SARS-CoV-2. Molnupiravir prevents SARS-CoV-2 from multiplying by causing damage to the genetic material of the virus.

2. What you need to know before you take [CV008 trade name]

Do not take [CV008 trade name]

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

Warnings and precautions

Talk to your healthcare provider about any concerns before you take molnupiravir.

Children and adolescents

Do not give this medicine to children and adolescents aged less than 18 years. The use and safety of [CV008 trade name] have not yet been studied in people aged less than 18 years.

Other medicines and [CV008 trade name]

Tell your health care provider if you are taking, have recently taken or might take any other medicines.

[†] Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

Pregnancy and breast-feeding

[CV008 trade name] is not recommended in pregnancy. [CV008 trade name] has not been studied in pregnancy and it is not known if [CV008 trade name] will harm your unborn baby. Animal studies with molnupiravir have shown harmful effects to the unborn animal.

If you are pregnant, think you may be pregnant, or you are planning to have a baby, ask your healthcare provider for advice. If you can become pregnant, you should use effective birth control while you are taking [CV008 trade name] and for 4 days after the last dose of [CV008 trade name].

If you are breast-feeding or are planning to breastfeed, tell your healthcare provider before taking this medicine. Breast-feeding is not recommended during treatment and for 4 days after the last dose of [CV008 trade name]. This is because it is not known if [CV008 trade name] gets into breast milk and may be passed on to the baby.

Advice for men

Men who are taking [CV008 trade name] must take care not to get their partners pregnant during treatment or for 3 months after their last dose. This is because it is not known if molnupiravir can affect their sperm and so cause harm to the baby.

Driving and using machines

No studies are available on the effects of [CV008 trade name] on the ability to drive and use machines. Do not drive or operate machinery if you feel dizzy or get other side effects that may make it dangerous to do so.

3. How to take [CV008 trade name]

Always take this medicine exactly as your healthcare provider has told you. Take it regularly at around the same times each day. Check with your healthcare provider if you are not sure.

The recommended dose for adults is 4 capsules every 12 hours for 5 days. Each [CV008 trade name] capsule contains 200 mg of molnupiravir.

[CV008 trade name] is not suitable for those aged under 18 years.

You can take [CV008 trade name] either with food or between meals.

Swallow the capsules whole with plenty of water. Do not open, break, or crush the capsules.

If you take more [CV008 trade name] than you should

If you take more [CV008 trade name] than you should or if somebody else takes it, contact your health care provider straightaway.

If you forget to take [CV008 trade name]

- You must not miss or skip doses of this medicine.
- If you forget to take a dose and it is still less than 10 hours after you should have taken it, take the dose at once and take the next dose at the usual time.
- If more than 10 hours have passed since you missed the dose, do 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, ask your health care provider.

Do not stop taking [CV008 trade name]

Do not stop taking [CV008 trade name] without first checking with your health care provider. Taking the medicine regularly and finishing the 5-day course will give you the best chance of not falling very ill with COVID-19.

4. Possible side effects

Like all medicines, this medicine can cause side effects but not everybody gets them.

Common side effects that can affect up to 1 in 10 people are:

- diarrhoea
- nausea (feeling sick)
- feeling dizzy
- headache

Uncommon side effects that can affect up to 1 in 100 people are:

- vomiting
- rash
- hives (itchy rash)

The following side effects can also occur, but it is not known how common they are:

- hypersensitivity (allergy)
- severe allergic reaction called anaphylaxis
- angioedema (rapid swelling under the skin in areas such as the face, throat, arms and legs)

Reporting of side effects

If you get a side effect, talk to your health care provider. This includes side effects not listed in this leaflet. You may also be able to report such effects directly to your national reporting system if one is available. By reporting side effects, you can help to improve the available information on this medicine.

5. How to store [CV008 trade name]

Store below 30°C.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the bottle/carton after “EXP”. The expiry date refers to the last day of that month.

Do not throw away any medicines in household waste. Ask your health care provider how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What [CV008 trade name] contains

- The active ingredient is molnupiravir. Each hard capsule contains 200 mg molnupiravir.
- The other ingredients of [CV008 trade name] used in the capsule fill are: microcrystalline cellulose; hydroxypropyl cellulose; croscarmellose sodium; magnesium stearate.
- The other ingredients used in the capsule shell are: gelatin; iron oxide yellow; titanium dioxide; FD&C blue #2/indigo carmine; hypromellose; carrageenan; potassium acetate.
- The other ingredients used in the printing ink are: shellac; propylene glycol; potassium hydroxide; titanium dioxide.

What [CV008 trade name] looks like and contents of the pack

White to off-white granular powder filled in size ‘0’ hard cellulose capsule with green opaque cap imprinted with “H” in white colour and green opaque body imprinted with “M11” in white colour.

[CV008 trade name] is available in:

- HDPE bottle. Pack size: 40 capsules.
- Alu/Alu blister card. Each blister card contains 10 tablets. Each blister card is packed in a carton. Pack size: 4 x 10 tablets.

Supplier and Manufacturer

Supplier

Hetero Labs Limited
Hetero Corporate, 7-2-A2, Industrial Estates
Sanath Nagar, Hyderabad
Telangana, 500 018

Manufacturer

Hetero Labs Limited, Unit-V
Survey No. 439, 440, 441 & 458,
TSIIC-Formulation SEZ, Polepally Village,
Jadcherla (Mandal), Mahaboob Nagar District

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For any information about this medicine, contact the supplier.

This leaflet was last revised in October 2022

Detailed information on this medicine is available on the World Health Organization (WHO) website: <https://extranet.who.int/pqweb/medicines>