

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/prequal/sites/default/files/document_files/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 non-severe COVID-19 in adults who could go on to develop severe illness.

You may be at more risk of developing severe illness if you:

- have been diagnosed with a condition causing your immune system not to function properly (immunodeficiency syndromes)
- are taking medicines that reduce the activity of your immune system, e.g. after you received an organ transplant or if you have an autoimmune illness
- have not been vaccinated against COVID-19

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 health care provider about any concerns before you take molnupiravir.

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

Children and adolescents

This medicine is not for use in 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.

Pregnancy and breast-feeding

You should not use [CV008 trade name] in pregnancy unless it is advised by your health care provider. [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. Do not breast-feed your baby during treatment with [CV008 trade name] and for 4 days after you have finished taking the tablets, 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]

Posology

Treatment with [CV008 trade name] should be started as soon as possible after diagnosing COVID-19 and within 5 days of the onset of COVID-19 symptoms.

The recommended dose of [CV008 trade name] for adults, including the elderly, is 800 mg (4 capsules) by mouth every 12 hours for 5 days.

Missed dose

If the patient does not take a dose of [CV008 trade name] at the right time and:

- the next dose is not due for at least 2 hours, the patient should take the missed dose at once and then take the next dose at the usual scheduled time.
- the next dose is due in less than 2 hours, the patient should skip the missed dose and instead take the next dose at the usual scheduled time.

The patient should not double the dose to make up for a missed dose.

Children and adolescents

[CV008 trade name] is not indicated for patients aged less than 18 years because its safety and efficacy have not been established (see also section 4.4).

Renal impairment

Dose adjustment is not necessary in patients with renal impairment. Renal function does not appreciably affect elimination of N4-hydroxycytidine (NHC), the active moiety of molnupiravir (see also section 5.2).

Hepatic impairment

Dose adjustment is not necessary in patients with hepatic impairment. NHC, the active moiety of molnupiravir is not expected to be significantly eliminated through the liver (see also section 5.2).

Method of administration

Capsules should be swallowed whole with water. The capsules should not be opened, crushed, or chewed. [CV008 trade name] can be taken with food or between meals.

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 (being sick)
- 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)
- erythema (reddening of the skin)
- pruritus (itching)

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 carton or bottle after 'EXP'. The expiry date refers to the last day of that month.

Do not use this medicine if you notice visible signs of deterioration that it is different from the description below.

Do not throw away any medicines in wastewater or 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 and 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 and potassium acetate.

- The other ingredients used in the printing ink are shellac, propylene glycol, potassium hydroxide and titanium dioxide.

There is too little sodium in this medicine to have any effect, even if you are on a low-sodium diet.

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

Hard cellulose capsules with an opaque green cap and body. They are printed in white on the cap with ‘H’ and on the body with ‘M11’. They contain white to off white granules.

Note: The capsules are to be swallowed whole, see section 3 on How to take [CV008 trade name].

[CV008 trade name] is available in:

Bottles: Opaque white plastic (HDPE) bottle containing 40 capsules. It contains a sachet of desiccant (drying material) and a piece of rayon wool to keep the capsules in place. The bottle has an opaque white plastic (polypropylene) screw cap with pulp liner.

Blister: Alu-Alu blister card, each containing 10 capsules. Available in cartons of 4 x 10 capsules.

Supplier and Manufacturer

Supplier

Hetero Labs Limited
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Manufacturer

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Jadcherla (Mandal), Mahaboob Nagar District
Telangana State, 509 301
India

For any information about this medicine, contact the local representative of the supplier.

This leaflet was last revised in March 2024

Detailed information on this medicine is available on the World Health Organization (WHO) website: <https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products>