

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

[CV014 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 [CV014 trade name] is and what it is used for
2. What you need to know before you take [CV014 trade name]
3. How to take [CV014 trade name]
4. Possible side effects
5. How to store [CV014 trade name]
6. Contents of the pack and other information

1. What [CV014 trade name] is and what it is used for

[CV014 trade name] contains the active substance molnupiravir. [CV014 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 [CV014 trade name]

Do not take [CV014 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 [CV014 trade name] have not yet been studied in people aged less than 18 years.

Other medicines and [CV014 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 [CV014 trade name] in pregnancy unless it is advised by your health care provider. [CV014 trade name] has not been studied in pregnancy and it is not known if [CV014 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 [CV014 trade name] and for 4 days after the last dose of [CV014 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 [CV014 trade name] and for 4 days after you have finished taking the tablets, because it is not known if [CV014 trade name] gets into breast milk and may be passed on to the baby.

Advice for men

Men who are taking [CV014 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 [CV014 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 [CV014 trade name]

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

The recommended dose for adults is 4 capsules every 12 hours for 5 days. Each [CV014 trade name] capsule contains 200 mg of molnupiravir.

You should start taking [CV014 trade name] within 5 days of getting symptoms of the illness.

[CV014 trade name] is not suitable for those aged under 18 years.

You can take [CV014 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 [CV014 trade name] than you should

If you take more [CV014 trade name] than you should or if somebody else takes it, contact your health care provider straightaway.

If you forget to take [CV014 trade name]

- You must not miss or skip doses of this medicine.
- If you have missed taking a dose at the usual time, and there are at least 2 hours to go until your next dose is due, take the dose at once and take the next dose at the usual time.
- If you missed your dose at the usual time and there are less than 2 hours to go until your next scheduled dose, skip the missed dose and just 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 [CV014 trade name]

Do not stop taking [CV014 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 (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 [CV014 trade name]

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

Do not store above 30°C.

Do not use this medicine after the expiry date stated on the carton or blister, 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 or 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 [CV014 trade name] contains

- The active ingredient is molnupiravir
- The other ingredient(s) of [CV014 trade name] is (are)
Capsule fill: Microcrystalline cellulose, croscarmellose sodium, hydroxypropyl cellulose *and* magnesium stearate
Capsule shell: Hypromellose, carrageenan, potassium chloride, FD&C blue #1/brilliant blue FCF, iron oxide yellow *and* titanium dioxide
Printing ink: Shellac *and* black iron oxide (E172)

What [CV014 trade name] looks like and contents of the pack

[CV014 trade name] is a hard cellulose capsule with opaque green cap and body which contain a white to off white granular powder. The capsules are printed in black on the cap with 'MOL' and on the body with '200'. [CV014 trade name] is package in an opaque white plastic (HDPE) bottle containing 40 capsules. The bottle has a white plastic (polypropylene) closure with induction sealing wad.

Supplier and Manufacturer

Supplier

Aurobindo Pharma Limited,
Plot No.2, Maitrivihar,
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Manufacturer

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

Country: INDIA

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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>