

## **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.*

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\* [https://extranet.who.int/pqweb/sites/default/files/documents/75%20SRA%20clarification\\_Feb2017\\_newtempl.pdf](https://extranet.who.int/pqweb/sites/default/files/documents/75%20SRA%20clarification_Feb2017_newtempl.pdf)

## Information for the patient

**[CV010 trade name]<sup>†</sup>**  
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 [CV010 trade name] is and what it is used for
2. What you need to know before you take [CV010 trade name]
3. How to take [CV010 trade name]
4. Possible side effects
5. How to store [CV010 trade name]
6. Contents of the pack and other information

#### 1. What [CV010 trade name] is and what it is used for

[CV010 trade name] contains the active substance molnupiravir. [CV010 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 [CV010 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 [CV010 trade name]

##### Do not take [CV010 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 [CV010 trade name] have not yet been studied in people aged less than 18 years.

### Other medicines and [CV010 trade name]

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

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<sup>†</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

### **Pregnancy and breast-feeding**

[CV010 trade name] is not recommended in pregnancy. [CV010 trade name] has not been studied in pregnancy and it is not known if [CV010 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 [CV010 trade name] and for 4 days after the last dose of [CV010 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 [CV010 trade name]. This is because it is not known if [CV010 trade name] gets into breast milk and may be passed on to the baby.

### **Advice for men**

Men who are taking [CV010 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 [CV010 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 [CV010 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 [CV010 trade name] capsule contains 200 mg of molnupiravir.

[CV010 trade name] is not suitable for those aged under 18 years.

You can take [CV010 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 [CV010 trade name] than you should**

If you take more [CV010 trade name] than you should or if somebody else takes it, contact your health care provider straightaway.

### **If you forget to take [CV010 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 [CV010 trade name]**

Do not stop taking [CV010 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 [CV010 trade name]**

Store protected from moisture, at a temperature not exceeding 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. The expiry date refers to the last day of that month.

Do not use this medicine if you notice signs of deterioration.

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 [CV010 trade name] contains**

The active ingredients is molnupiravir.

The other ingredient(s) of [CV010 trade name] are:

<i>Capsule fill</i>	Microcrystalline cellulose Hydroxypropyl cellulose Croscarmellose sodium Magnesium stearate
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<i>Capsule shell</i>	Hypromellose Carrageenan Potassium acetate Titanium dioxide
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<i>Printing ink</i>	Shellac Propylene glycol Black iron oxide Potassium hydroxide
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### **What [CV010 trade name] looks like and contents of the pack**

[CV010 trade name] capsule consists of white opaque cap imprinted with 'EM66' in black ink and white, opaque body imprinted with 'EM66' in black ink containing white to off-white granular powder.

[CV010 trade name] is supplied in white, opaque, HDPE bottle with white, opaque, polypropylene closure containing 40 capsules in each bottle.

**Supplier and Manufacturer**

***Supplier***

Emcure Pharmaceuticals Ltd  
T-184, MIDC, Bhosari  
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Email [order@emcure.co.in](mailto:order@emcure.co.in)

***Manufacturer***

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**This leaflet was last revised in January 2023**

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