

Molnupiravir: Fact Sheet for Healthcare Givers and Recipients

APPROVED FOR RESTRICTED USE IN EMERGENCY SITUATION IN PUBLIC INTEREST

CIPLA LTD. MOLNUPIRAVIR 200MG CAPSULE IS USED TO TREAT ADULT PATIENTS WITH COVID-19, WITH SPO₂ >93% AND WHO HAVE HIGH RISK OF PROGRESSION OF THE DISEASE INCLUDING HOSPITALIZATION OR DEATH

Molnupiravir 200mg Capsule has been given restricted use license for emergency situation. It does not have a marketing authorization, however, this approval for the restricted use in emergency situation grants permission for Molnupiravir to be used to treat adults with COVID-19 who do not require supplemental oxygen and who are at increased risk of developing severe COVID-19.

Reporting of side effects

As with any new medicine, Molnupiravir will be closely monitored to allow quick identification of new safety information. You can help by reporting any side effects you may get after treatment with Molnupiravir, to Cipla Ltd. at drugsafety@ciplaltd.com. You can also report side effects directly via the National Pharmacovigilance Program of India (PvPI) by calling on 1800 180 3024 or you can report to Cipla Ltd on 1800 267 7779. By reporting side-effects, you can help provide more information on the safety of this product. All adverse events reported will be entered in COWIN App by the health care provider. For more information read this fact sheet carefully.

You are being offered the Cipla Ltd. Molnupiravir 200mg Capsule to treat COVID-19. This Fact Sheet contains information to help you understand the risks and benefits of the Molnupiravir 200mg Capsule, which you may receive because there is currently a pandemic of COVID-19 disease.

Molnupiravir is an investigational oral antiviral agent currently being studied in clinical trial for the treatment of adults with COVID-19 who do not require supplemental oxygen and who are at increased risk of developing severe COVID-19.

Please read this Fact Sheet for information about the Cipla Molnupiravir 200mg Capsule. Talk to the healthcare provider if you have any questions.

What You Need to Know Before You Get Molnupiravir

What is Covid-19?

COVID-19 disease is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before in humans. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

What is Molnupiravir?

Molnupiravir is an investigational oral antiviral agent which has been studied in a Phase 3 trial for the treatment of adults with COVID-19 who do not require supplemental oxygen and who are at increased risk of developing severe COVID-19.

Molnupiravir is authorized for the restricted emergency use of Molnupiravir by CDSCO (Indian regulatory authority) for the treatment of adult patients with covid-19, with SpO₂ >93% and who have high risk of progression of the disease including hospitalization or death under an EUA.

Molnupiravir is not authorized -

- for use in patients less than 18 years of age
- for initiation of treatment in patients requiring immediate hospitalization due to COVID-19 at that stage, (however, if it was initiated before hospitalization due to COVID 19, it may be continued).
- for use for longer than 5 consecutive days.
- for pre-exposure or post-exposure prophylaxis for prevention of COVID-19
- for pregnant women
- Females of childbearing potential should use a reliable method of contraception correctly and consistently, as applicable, for the duration of treatment and for 4 days after the last dose of molnupiravir.
- Males of reproductive potential who are sexually active with females of child bearing potential should use a reliable method of contraception correctly and consistently during treatment and for at least 3 months after the last dose

What You Need to Know Before You Use Molnupiravir

Do not use molnupiravir

- if you are allergic to molnupiravir or any of the other ingredients of this medicine.

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 molnupiravir in persons aged less than 18 years has not yet been studied.

Other medicines and molnupiravir

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding

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

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

If you are breast-feeding or are planning to breastfeed, tell your doctor before taking this medicine. **Breast-feeding is not recommended during treatment and for 4 days after the last dose of molnupiravir.** This is because it is not known if molnupiravir 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.

Who Should Get Molnupiravir?

Molnupiravir can be used to treat adult patients with covid-19, with SpO₂ >93% and who have high risk of progression of the disease including hospitalization or death.

What Are the Ingredients in Molnupiravir?

Capsule Composition:

Active substance: Each capsule contains 200mg Molnupiravir.

Excipients: Microcrystalline cellulose, Hydroxypropyl cellulose, Croscarmellose sodium, Magnesium stearate, Capsule shells.

How is Molnupiravir Given?

Always take this medicine exactly as your doctor has told you. Do not change the dose or stop taking Molnupiravir without first talking to your healthcare provider. Check with your doctor or healthcare provider.

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

How much to take

The recommended dose of Molnupiravir is four 200 mg capsules, twice daily 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.

If you take more molnupiravir than you should

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

If you forget to take molnupiravir

- 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 molnupiravir

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

If you have any further questions on the use of this medicine, ask your doctor or health care provider.

Has Molnupiravir Been Used Before?

Molnupiravir is still undergoing clinical trials.

What Other Treatment Choices Are There?

Like molnupiravir, CDSCO has given and may give restricted emergency use authorisations to few other medicines to treat adult patients with covid-19. Your healthcare provider may talk with you about other treatment choices available or clinical trials you may be eligible for.

What If I Decide Not to Take Molnupiravir?

If you decide not to take molnupiravir, your doctor will give you an alternate medicine for your medical condition.

What Are the Risks of Molnupiravir?

In an ongoing Phase 3 study of 386 patients with mild to moderate COVID-19, treated with molnupiravir, the most common adverse reactions reported during treatment and during 14 days after the last dose were diarrhoea, nausea, dizziness and headache all of which were mild or moderate.

Common (may affect upto 1 in 10 people)

- dizziness
- headache
- diarrhoea
- nausea

Uncommon (may affect upto 1 in 100 people)

- vomiting
- rash
- hives

In an ongoing Phase 3 study being conducted in India, of 823 patients treated with Molnupiravir as add on to Standard supportive Care for treatment of Mild Patients with COVID-19 Disease, adverse reactions reported were

Uncommon (may affect upto 1 in 100 people)

- nausea

Rare (may affect upto 1 in 1000 people)

- eye irritation
- abdominal pain
- weakness
- sinusitis
- muscle pain
- headache
- cough
- fever

What Should I Do About Side Effects?

If you experience a severe allergic reaction, call or go to the nearest hospital.

Call the healthcare provider if you have any side effects that bother you or do not go away.

In addition, you can report side effects after treatment to Cipla Ltd at drugsafety@cipla.com.

Can I Receive Molnupiravir with Other Medication?

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Molnupiravir and other medicines may affect each other causing possible serious side effects. Molnupiravir may affect the way other medicines work, and other medicines may affect how Molnupiravir works.

Your healthcare provider can tell you if it is safe to take Molnupiravir with your other medicines. Do not start or stop any other medicines during treatment with Molnupiravir without talking to your healthcare provider first.

Know the medicines you take. Keep a list of your medicines to show your healthcare provider and pharmacist when you get a new medicine.

How Can I Learn More?

- Ask the healthcare provider.
- Contact your local or state public health department.

Details of manufacturer

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Revised: 31 December 2021