

Molnupiravir (Lagevrio®)

Adult (18 years and over)
Informed consent: patient information

URN:

Family name:

Given name(s):

Address:

Date of birth:

Sex: M F I

A copy of this patient information sheet should be given to the patient/substitute decision-maker to read carefully and allow time to ask any questions about the treatment. A copy should be included in the patient's medical record.

What is molnupiravir and how will it help me/the patient?

Molnupiravir (mol-noo-PIRRA-veer) is a medication that was developed to treat COVID-19. It is also known by the brand name of Lagevrio®. It works by blocking the ability of the virus from being able to make more copies of itself. This can help stop infected people from getting seriously sick.

Molnupiravir reduces the risk of needing to go to hospital or dying from COVID-19 **if used within 5 days of symptoms first appearing.**

In Australia, molnupiravir is provisionally approved by the Therapeutic Goods Administration (TGA) to treat adults with COVID-19 who are at risk of becoming seriously ill. This medication is for patients who are not in hospital and not using oxygen treatment.

Molnupiravir was studied in the MOVE-OUT trial.¹ This trial helped inform the guidelines of the National COVID-19 Clinical Evidence Taskforce, which were used to create this patient information.



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Preparing for the treatment

A doctor will discuss the risks and benefits of molnupiravir treatment with you or your substitute decision-maker and must obtain consent before it is given. The doctor will need to know:

- any existing medical conditions
- any previous allergies to medications
- the possibility that you are pregnant or have plans for a future pregnancy
- if you are breastfeeding
- any recent vaccinations or plans for COVID-19 vaccinations and boosters.

Because molnupiravir is a new medicine, information about how well it works, and its safety is still being collected. It is important that you and your substitute decision-maker understand when and why molnupiravir may be useful. Your doctor will discuss with you about how well it works and how safe it is in your condition.

What should I know before I take molnupiravir?

Pregnancy and reproduction

Molnupiravir should not be taken in pregnancy. Molnupiravir has not been studied in pregnancy in humans, but studies have shown that molnupiravir can have harmful effects on unborn animals. If there is a chance you could be pregnant, you should talk to your doctor about having a pregnancy test before taking molnupiravir. You should use a reliable method of contraception (birth control) or not have sex **while taking molnupiravir and for 4 days after the last dose** if there is a possibility you could become pregnant.

What about men? It is not known if molnupiravir can affect sperm in humans. Animal studies have not shown effects on fertility. If you are a male who is sexually active with a partner who could become pregnant, you should use a reliable method of contraception (birth control) **during treatment and for 3 months after the last dose of molnupiravir.**

Breastfeeding

It is not known if molnupiravir gets into breast milk and will be passed onto the baby. Tell your doctor if you are breastfeeding or plan to breastfeed before taking molnupiravir.

Breastfeeding is not recommended **during treatment and for 4 days after the last dose** of molnupiravir.



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How do I take molnupiravir?

Molnupiravir is given as capsules, taken twice a day for 5 days. The usual dose is 4 capsules taken every 12 hours (for example at 8am and at 8pm). These capsules can be taken with or without food and should be swallowed whole. It is generally recommended not to open, break or crush the capsules. For patients with swallowing difficulties, the capsules may be administered via a nasogastric tube, with advice from a healthcare professional.

Do not stop taking this medicine without talking to your doctor first.

What if I forget to take a dose?

You should take molnupiravir regularly at the same times each day. It is important that you do not miss or skip doses of this medicine. If you do miss a dose:

- if it has been less than 10 hours since you were meant to take the dose, take it as soon as you remember
- if it has been more than 10 hours since you were meant to take the dose, skip the missed dose and take your next dose at scheduled time.

Do not take a double dose to make up for the dose you missed. Call your doctor or pharmacist if you are not sure what to do.

What are the risks of taking molnupiravir?

All medicines have side effects. Sometimes they are serious, but most of the time they are not. It can also be hard to tell if the side effects are from the molnupiravir or are symptoms of COVID-19.

Some of the possible side effects and what to do are listed below.

Possible side effects of molnupiravir

- diarrhoea
- nausea
- dizziness.

Speak to your doctor if you have any of these side effects and they worry you.

It is possible (although unlikely) that other, yet unknown side effects may occur with molnupiravir. Side effects should be reported to the doctor directly. Your doctor or healthcare provider will report the details of the reaction to the Therapeutic Goods Administration (TGA) and document this in your medical record.

What are the risks of not having molnupiravir?

Molnupiravir is used for the early treatment of COVID-19 in high-risk patients with other medical conditions to reduce the need for hospital admission and prevent progression to severe illness or death.

The decision to take molnupiravir will depend on your age, existing medical conditions and if you are vaccinated against COVID-19 or not.

In the MOVE-OUT trial looking at effectiveness of molnupiravir, the group of patients who received the medication had a 30 per cent less chance of needing to go to hospital compared to the group of patients who did not have molnupiravir.¹

If you provide consent, you have the right to change your mind at any time prior to taking the medication. Please contact the doctor/clinician to discuss.

Are there alternative treatments?

There are other medications that can be used for COVID-19. Some are intravenous (IV) infusions given through a vein and some are tablets. Your doctor will discuss the best option for you based on your health conditions, availability of the medications and your preferences.

What should I expect after treatment?

Some patients may still develop severe COVID-19 after molnupiravir. It is important that you monitor symptoms and call your local doctor, call 13 HEALTH (13 43 25 84) or go to your nearest hospital if you start to feel worse due to COVID-19.

When can I get vaccinated?

Having molnupiravir won't affect when your next vaccination is scheduled after you recover from COVID-19.

How should I store my medicine?

You should store your pills (capsules) in the original bottle in a cool dry place, below 30°C, away from moisture, heat, or sunlight. For example, do not store it:

- in the bathroom or near a sink, or
- in the car or on a window sill.

Keep it where young children cannot reach it.

Where can I find support or more information?

- If your symptoms get worse – call **13 HEALTH (13 43 25 84)**
- If you have serious symptoms, like difficulty breathing – **call 000 and ask for an ambulance.**
- Medication for treating COVID-19. Health Direct – Free Australian health advice you can count on. www.healthdirect.gov.au/covid-19-medication.
- Merck Sharp & Dohme (Australia) Pty Ltd. Australian Consumer Medicines Information Lagevrio® capsules (molnupiravir). Therapeutic Goods Administration. Published January 2022. www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2022-CMI-01048-1&d=20220201172310101.
- National COVID-19 Clinical Evidence Taskforce. Australian Guidelines for the Clinical Care of people with COVID-19. <https://covid19evidence.net.au/#living-guidelines>.

References:

1. Bernal AJ, Gomes da Silva MM, Musungaie DB. Molnupiravir for oral treatment of Covid-19 nonhospitalized patients. N Engl J Med. 2021. Available at: www.nejm.org/doi/pdf/10.1056/NEJMoa2116044?articleTools=true.