

LAGEVRIO® Capsules

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

- ▼ This is a new medicine. Please report any side effects that you may experience with this medicine. See the [full CMI](#) for further details.

1. Why am I taking LAGEVRIO?

LAGEVRIO contains the active ingredient molnupiravir. You are being given LAGEVRIO for the treatment of coronavirus disease (COVID-19). LAGEVRIO may help you to feel better and stay out of hospital. More information can be found in Section [1. Why am I taking LAGEVRIO?](#) in the full CMI.

2. What should I know before I take LAGEVRIO?

Do not take LAGEVRIO if you have ever had an allergic reaction to molnupiravir or any of the ingredients listed at the end of this CMI.

LAGEVRIO is not recommended in pregnancy.

If there is a chance you might be pregnant, talk to your doctor about having a pregnancy test prior to commencing LAGEVRIO. Use effective birth control while you are taking LAGEVRIO and for 4 days after the last dose if there is a possibility of you getting pregnant. If you are a male who is sexually active with a partner who has the potential to become pregnant, use a reliable method of contraception during treatment and for 3 months after the last dose of LAGEVRIO.

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

Talk to your doctor if you have any other medical conditions, take any other medicines, have any allergies, or are pregnant or plan to become pregnant or are breastfeeding or plan to breastfeed.

More information can be found in Section [2. What should I know before I take LAGEVRIO?](#) in the full CMI.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins, or supplements that you buy without a prescription from your pharmacy, supermarket, or health food shop.

More information can be found in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take LAGEVRIO?

- Take LAGEVRIO exactly as your doctor tells you.
- Take 4 capsules of LAGEVRIO every 12 hours (for example, at 8 am and at 8 pm).
- Take LAGEVRIO for 5 days.
- Take LAGEVRIO with or without food.

More information can be found in Section [4. How do I take LAGEVRIO?](#) in the full CMI.

5. What should I know while taking LAGEVRIO?

Things you should do	<ul style="list-style-type: none">• Tell the doctor, dentist, or pharmacist you visit that you are taking LAGEVRIO.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking this medicine without talking to your doctor first.
Looking after your medicine	<ul style="list-style-type: none">• Store LAGEVRIO in the original bottle in a cool dry place below 30°C, away from heat or sunlight.

More information can be found in Section [5. What should I know while taking LAGEVRIO?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If they do occur, they are usually minor and temporary. Do not be alarmed by this list. You may not experience any of them. The most common side effects (unintended or undesirable effects) of LAGEVRIO in adults are diarrhoea, nausea, and dizziness. More information, including what to do if you have any side effects, can be found in Section [6. Are there any side effects?](#) in the full CMI.

- ▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

LAGEVRIO® Capsules

Active ingredient(s): *molnupiravir*

LAGEVRIO has **provisional approval** to treat COVID-19 in adults who are at increased risk for hospitalisation or death. The decision to approve this medicine has been made on the basis of results of data available at the time of provisional approval. More evidence is required to be submitted when available to fully confirm the benefit and safety of LAGEVRIO for this use.

Consumer Medicine Information (CMI)

This leaflet provides important information about taking LAGEVRIO. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking LAGEVRIO.**

Where to find information in this leaflet:

- [1. Why am I taking LAGEVRIO?](#)
 - [2. What should I know before I take LAGEVRIO?](#)
 - [3. What if I am taking other medicines?](#)
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[4. How do I take LAGEVRIO?](#)

[5. What should I know while taking LAGEVRIO?](#)

[6. Are there any side effects?](#)

[7. Product details](#)

1. Why am I taking LAGEVRIO?

LAGEVRIO contains the active ingredient molnupiravir.

LAGEVRIO has provisional approval to treat COVID-19 in adults who are at increased risk for hospitalisation or death.

The decision to approve this medicine has been made on the basis of results of data available at the time of provisional approval. More evidence is required to be submitted when available to fully confirm the benefit and safety of LAGEVRIO for this use.

LAGEVRIO is an antiviral drug that works against the virus that causes COVID-19.

You are being given LAGEVRIO for the treatment of coronavirus disease 2019 (COVID-19). LAGEVRIO may help you to feel better and stay out of hospital.

What is COVID-19?

- COVID-19 is caused by a virus called SARS CoV-2.
- You can get COVID-19 through contact with another person who has the virus.

COVID-19 illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, serious illness including breathing problems can happen and may cause some of your other medical conditions to become worse.

Older people and people of all ages with severe, long lasting (chronic) medical conditions like heart disease, lung disease, obesity, and diabetes, for example seem to be at higher risk of being hospitalised for COVID-19.

What are the symptoms of COVID-19?

The symptoms of COVID-19 may include fever, cough, and shortness of breath.

2. What should I know before I take LAGEVRIO?

Do not take LAGEVRIO if:

- You are allergic to molnupiravir, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can take this medicine.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition

- have any allergies

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and Reproduction

- Animal studies with molnupiravir have shown harmful effects to the unborn animal.
- LAGEVRIO has not been studied in pregnancy in humans and it is not known if LAGEVRIO will harm your baby while you are pregnant.
- LAGEVRIO is not recommended in pregnancy. Discuss the need for a pregnancy test with your doctor if you are of childbearing potential and sexually active.
- Tell your doctor if you are pregnant or plan to become pregnant.
- Use effective birth control while you are taking LAGEVRIO and for 4 days after the last dose of LAGEVRIO if there is a possibility of you getting pregnant.
- Animal studies have not shown effects on fertility. It is not known how LAGEVRIO may affect sperm in humans. If you are a male who is sexually active with a partner who has the potential to become pregnant, use a reliable method of contraception during treatment and for 3 months after the last dose of LAGEVRIO.

Breastfeeding

- It is not known if LAGEVRIO gets into breast milk and will be passed to the baby.
- Tell your doctor if you are breastfeeding or plan to breastfeed before taking LAGEVRIO.
- Breastfeeding is not recommended during treatment and for 4 days after the last dose of LAGEVRIO.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins, or supplements that you buy without a prescription from your pharmacy, supermarket, or health food shop.

Some medicines may interfere with LAGEVRIO and affect how it works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect LAGEVRIO.

4. How do I take LAGEVRIO?

How to take LAGEVRIO

- Take LAGEVRIO exactly as your doctor tells you.
- Take 4 capsules of LAGEVRIO every 12 hours (for example, at 8 am and at 8pm).
- Take LAGEVRIO every day for 5 days.

- Take LAGEVRIO with or without food.

If you forget to take LAGEVRIO

LAGEVRIO should be taken regularly at the same times each day. It is important that you do not miss or skip doses of this medicine. What to do if you miss a dose?

- If it has been less than 10 hours since the missed dose, take it as soon as you remember.
- If it has been more than 10 hours since the missed dose, skip the missed dose and take your dose at the next 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.

If you take too much LAGEVRIO

If you think that you have taken too much LAGEVRIO, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- call your doctor or pharmacist, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking LAGEVRIO?

Things you should do

Tell the doctor, dentist, or pharmacist you visit that you are taking LAGEVRIO and follow their advice.

Things you should not do

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

Looking after your medicine

Follow the instructions on the carton on how to store your medicine properly.

Store LAGEVRIO in the original bottle in a cool dry place below 30°C, away from heat or sunlight; for example, do not store it:

in the bathroom or near a sink, or

in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Common side effects	What to do
<ul style="list-style-type: none">• diarrhoea• nausea• dizziness	Speak to your doctor if you have any of these side effects and they worry you.

Allergic reactions can happen in people taking LAGEVRIO, even after only 1 dose. Stop taking LAGEVRIO and call your healthcare provider right away if you get any of the following symptoms of an allergic reaction:

- hives
- rapid heartbeat
- trouble swallowing or breathing
- swelling of the mouth, lips or face
- throat tightness
- hoarseness
- skin rash

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What LAGEVRIO contains

Active ingredient (main ingredient)	Molnupiravir 200 mg
Other ingredients (inactive ingredients)	croscarmellose sodium hypromellose

magnesium stearate
microcrystalline cellulose
purified water

Capsule shell:

hypromellose
iron oxide red
titanium dioxide

White ink on the capsule:

tert-butyl alcohol
ethanol absolute
isopropyl alcohol
potassium hydroxide
propylene glycol
purified water
shellac
strong ammonia solution
titanium dioxide

Do not take this medicine if you are allergic to any of these ingredients.

What LAGEVRIO looks like

LAGEVRIO is supplied in a bottle containing 40 capsules.

LAGEVRIO is available as a Swedish Orange opaque capsule with corporate logo and “82” printed with white ink for oral administration (AUST R 372650).

Who distributes LAGEVRIO

Merck Sharp & Dohme (Australia) Pty Limited
Level 1, Building A, 26 Talavera Road
Macquarie Park NSW 2113

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