

# Information for patients, family and carers

## Use of molnupiravir (Lagevrio®) for the treatment of COVID-19 in adults

This information leaflet includes important information about the medicine molnupiravir (Lagevrio®) when used to treat COVID-19.

### What is the potential benefit of Lagevrio® for COVID-19?

Lagevrio® belongs to a group of medicines called antivirals. It works by targeting the virus that causes COVID-19 and preventing it from infecting healthy human cells. Lagevrio® has been shown to reduce the risk of severe infection, hospitalisation and death in people with mild to moderate COVID-19 with one or more risk factors.

Lagevrio® has been provisionally approved in Australia to treat adults with COVID-19 who do not need oxygen but are at risk of severe illness and hospitalisation. This medicine is not intended to be a replacement for vaccination against COVID-19.

### What should be considered when using Lagevrio® for COVID-19?

Lagevrio® is a new medicine and provisionally (not fully) registered to treat COVID-19 in Australia, so information about how well it works and how safe it is, is being collected. It is important that patients and their carers understand when and why Lagevrio® may be useful. Your doctor will provide more information about how well it works and how safe it is in your condition.

The use of Lagevrio® for COVID-19 is new and it is important you provide your formal consent before Lagevrio® treatment begins. You can always change your mind about treatment with Lagevrio® and withdraw consent at any time.

### What should your doctor know before Lagevrio® is used for COVID-19?

Your doctor should know about:

- any medical conditions you have
- any kidney or liver problem
- previous allergic reactions to any medicine
- all medicines including over-the-counter and complementary medicines e.g. vitamins, minerals, herbal or naturopathic medicines that you are taking or have recently taken
- the possibility of pregnancy or plans for pregnancy (for both male and female patients)
- if you are breastfeeding or plan to breastfeed

### How is Lagevrio® taken?

- Take 4 capsules of Lagevrio® (molnupiravir) every twelve hours (for example at 8 am and at 8 pm).
- Take Lagevrio® for 5 days. It is important that you complete the full 5 days of treatment. Do not stop taking Lagevrio® before completing the full 5 days of treatment, even if you feel better.
- Lagevrio® can be taken with a full glass of water, with or without food.
- Lagevrio® must be swallowed whole. Do not open, break, or crush the capsule. If you cannot swallow capsules whole, please inform your doctor or pharmacist.
- Lagevrio® is most effective when commenced as soon as possible after a diagnosis of COVID-19 has been made and within five days of symptom onset.

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Use this calendar to help keep track of your doses. Note, if your first dose was in the evening on Day 1 your last dose may be in the morning on Day 6.

	Day 1	Day 2	Day 3	Day 4	Day 5
	Date:	Date:	Date:	Date:	Date:
	.....	.....	.....	.....	.....
<b>Morning</b>  4 x 200 mg capsules Time: .....					
<b>Evening</b>  4 x 200 mg capsules Time: .....					

## 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 double the dose of Lagevrio® to make up for a missed dose.

## If you take too much Lagevrio®

If you think you have taken too much Lagevrio®, you may need urgent medical attention. You should immediately:

- Contact your doctor, **OR**
- Phone the Poisons Information Centre (by calling 13 11 26), **OR**
- Go to the Emergency Department of your nearest hospital.

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

## Are there special precautions with Lagevrio® treatment?

Use with other medicines – Lagevrio® is a new medicine. Some medicines may interfere with Lagevrio® and affect how it works. It is important that your doctor and other health professionals (such as the pharmacist or nurse) are informed about all medicines normally taken or planned. This includes over-the-counter and complementary medicines e.g., vitamins, minerals, herbal or naturopathic medicines that you are taking or have recently taken. The doctor and pharmacist will check for potential medicine interactions before Lagevrio® is started and when it is stopped.

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### Fertility, pregnancy and breastfeeding

#### *For men who are sexually active:*

- Animal studies have not shown effects on fertility in male animals during Lagevrio® treatment. It is not known if Lagevrio® affects sperm.
- Lagevrio® may harm a foetus if your partner were to fall pregnant while you are taking this medication and for 3 months after.
- Use a reliable form of contraception during treatment with Lagevrio® and for 3 months after the last dose of Lagevrio®.

#### *For pregnant women:*

- Lagevrio® has not been studied in pregnancy in humans. Lagevrio® was studied in pregnant animals only, where harmful effects to the unborn animal were found.
- Lagevrio® is **not recommended** in pregnancy.

#### *For women who can become pregnant:*

- Animal studies have not shown effects on fertility in female animals during Lagevrio® treatment.
- Your doctor may do a pregnancy test to see if you are pregnant before starting treatment with Lagevrio®.
- Taking Lagevrio® at the time you fall pregnant may harm the foetus.
- A reliable form of contraception should be used during treatment with Lagevrio® and for 4 days after the last dose of Lagevrio®. Consult your doctor or pharmacist about reliable contraception methods.
- Tell your doctor immediately if you become pregnant or think you may be pregnant during treatment with Lagevrio®.

#### *For women who are breastfeeding:*

- Breastfeeding is not recommended during treatment with Lagevrio® and for 4 days after the last dose has been taken. If you are breastfeeding or planning to breastfeed, discuss options and your specific situation with your doctor before taking Lagevrio®.

### **What are the side effects of Lagevrio®?**

All medicines have side effects. Sometimes they are serious, but most of the time they are not, and many of them disappear with time or when treatment is stopped. Medical treatment may be needed for some side effects. Side effects may not be experienced. Some side effects that might be experienced during treatment with Lagevrio® are shown below. Other, currently unknown, side effects with Lagevrio® may occur when it is used in people with COVID-19. Because Lagevrio® is a new medicine, patients who receiving this medicine will be monitored closely.

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Possible side effects of Lagevrio®	What to do
Side effects which may appear after receiving Lagevrio®: <ul style="list-style-type: none"><li>• Diarrhoea</li><li>• Nausea</li><li>• Dizziness.</li></ul>	Tell your doctor if these symptoms occur.
Allergic reactions, symptoms may include: <ul style="list-style-type: none"><li>• Shortness of breath</li><li>• Swelling of the face, lips, tongue or any parts of the body</li><li>• Severe skin rash, itching, hives.</li></ul>	Contact 000 or go straight to the Emergency Department at your nearest hospital.

**Please note:** This is not a complete list of all side effects. Because Lagevrio® is a new medicine, it is important to report side effects to the doctor directly and/or to the Therapeutic Goods Administration at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems)

**If you are experiencing any side effects, including any of the ones listed above or are feeling unwell in any way, please call the healthcare worker on the phone number below for advice.**

**Name of healthcare worker to call:** \_\_\_\_\_  
**Telephone number:** \_\_\_\_\_

For more information about Lagevrio®

- refer to the Australian [Consumer Medicines Information](#)
- call the [NPS Medicines Line](#) – 1300 633 424

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