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Molnupiravir (Lagevrio®) Patient Information

This information leaflet includes important information about the medicine called molnupiravir (Lagevrio®) when used in the treatment of COVID-19.

NOTE: Having COVID-19 infection and being treated does not offer the same protection as vaccination.

What is the medication used for?

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.

Lagevrio® must not be used:

- to treat patients with severe or critical COVID-19 infection
- to treat patients who have had symptoms for more than 5 days
- as a preventive medicine to stop COVID-19 infection from occurring
- for longer than 5 days in a row
- to treat children and adolescents less than 18 years of age.

Do not give your medicine to anyone else, even if they have the same condition as you.

What does this medication do?

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 one or more risk factors, who contract mild to moderate COVID-19.

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

Lagevrio[®] is a new medicine that is 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 health practitioner 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 for you to provide your

What should the health practitioner know before Lagevrio[®] is used in COVID-19?

The health practitioner should know about:

- any medical conditions you have
- 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
- recent vaccinations or plans to get vaccinated

formal consent before Lagevrio[®] treatment begins. You can always change your mind about treatment with Lagevrio[®] and withdraw your consent at any time.

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How is Lagevrio® taken?

- Take 4 capsules of Lagevrio[®] (molnupiravir) every 12 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 health practitioner.
- Lagevrio[®] is most effective when commenced as soon as possible after a diagnosis of COVID-19 has been made and within 5 days of symptom onset.

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:
Morning 4 x 200 mg capsules Time:					
Evening 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 health practitioner, OR
- phone the Poisons Information Centre (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 practitioners (such as the pharmacist or nurse) are informed about all medicines that you are taking or have recently taken. This includes over-the-counter and complementary medicines e.g., vitamins, minerals, herbal or naturopathic medicines. The health practitioner (e.g. doctor and/or pharmacist) will check for potential medicine interactions before Lagevrio® is started and when it is stopped.

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 health practitioner 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 health practitioner about reliable contraception methods.
- Tell your health practitioner 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 health practitioner before taking Lagevrio®.

For further information about the use of this medicine in pregnancy, breastfeeding or family planning, please contact the King Edward Memorial Hospital Obstetric Medicines Information Service on 6458 2723.

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.

Possible side effects of Lagevrio [®] :	What to do
Side effects which may appear after receiving Lagevrio®: Diarrhoea Nausea Dizziness.	Tell your health practitioner if these symptoms occur.
Allergic reactions, symptoms may include: • Shortness of breath • Swelling of the face, lips, tongue or any parts of the body • Severe skin rash, itching, hives.	Contact 000 or go straight to the Emergency Department at your nearest hospital.

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 health practitioner directly and/or to the Therapeutic Goods Administration at 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 health practitioner on the phone number below for advice.				
Name of health practitioner to call:				
Telephone number:				

What should I do if my COVID-19 symptoms get worse?

Call your healthcare provider if you have any questions or concerns.

Call 000 immediately if you experience severe symptoms of COVID-19, such as:

- difficulty breathing
- severe chest pain
- feelings of disorientation or confusion
- loss of consciousness.

If you have any questions about this medication, call your health practitioner (e.g. doctor or pharmacist).

What should I do after I finish my treatment?

Treatment does not shorten your isolation time. You are still considered to be contagious while you are taking this medicine. Follow all Public Health guidelines for isolation. For information about isolation please refer to the Healthy WA website.

https://www.healthywa.wa.gov.au/Articles/A_E/Coronavirus/Quarantine-and-isolation

This document can be made available in alternative formats on request for a person with disability.

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