

Package leaflet: Information for the patient

Lagevrio® 200 mg hard capsules molnupiravir

▼ 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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, or pharmacist, or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Lagevrio is and what it is used for
2. What you need to know before you take Lagevrio
3. How to take Lagevrio
4. Possible side effects
5. How to store Lagevrio
6. Contents of the pack and other information

1. What Lagevrio is and what it is used for

Lagevrio contains the active substance molnupiravir. Lagevrio is an antiviral medicine used to treat mild to moderate COVID-19 (caused by SARS-CoV-2) in adults who are at risk for developing severe illness.

Lagevrio may help people with COVID-19 stay out of the hospital and feel better.

2. What you need to know before you take Lagevrio

Do not take Lagevrio

- if you are allergic to molnupiravir or any of the other ingredients of this medicine (listed in section 6).

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

Other medicines and Lagevrio

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. **Lagevrio is not recommended in pregnancy.** Lagevrio has not been studied in pregnancy and it is not known if Lagevrio 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 Lagevrio and for 4 days after the last dose of Lagevrio.

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 Lagevrio.** This is because it is not known if Lagevrio 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.

Lagevrio contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose of 4 capsules, that is to say essentially 'sodium-free'.

3. How to take Lagevrio

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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

How much to take

The recommended dose of Lagevrio is four 200 mg capsules, every 12 hours 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 Lagevrio than you should

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

If you forget to take Lagevrio

- 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 Lagevrio

Do not stop taking Lagevrio 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 pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common: may affect up to 1 in 10 people

- diarrhoea
- nausea
- feeling dizzy
- headache

Uncommon: may affect up to 1 in 100 people

- vomiting
- rash
- hives

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Coronavirus Yellow Card Reporting site at <https://coronavirus-yellowcard.mhra.gov.uk> or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Lagevrio

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and bottle label after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions. Store in the original package.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Lagevrio contains

The active substance is molnupiravir. Each hard capsule contains 200 mg of molnupiravir.

The other ingredients are:

Capsule content: Croscarmellose sodium (E468), hydroxypropyl cellulose (E463), magnesium stearate (E470b), microcrystalline cellulose (E460).

Capsule shell: Hypromellose (E464), titanium dioxide (E171), red iron oxide (E172).

Printing ink: Butyl alcohol, dehydrated alcohol, isopropyl alcohol, potassium hydroxide, propylene glycol (E1520), purified water, shellac, strong ammonia solution, and titanium dioxide (E171).

What Lagevrio looks like and contents of the pack

Lagevrio 200 mg hard capsule is a Swedish Orange opaque, size 0 (approximately 21.7 mm x 7.6 mm) hard capsule, printed with MSD corporate logo on the cap and “82” on the body in white ink.

Lagevrio 200 mg hard capsules are supplied in high-density polyethylene (HDPE) bottles with a polypropylene cap containing 40 capsules.

Marketing Authorisation Holder and Manufacturer**Marketing Authorisation Holder:**

Merck Sharp & Dohme (UK) Limited
120 Moorgate
London
EC2M 6UR
United Kingdom

Manufacturer:

Merck Sharp & Dohme B.V.
Waarderweg 39
2031 BN Haarlem
The Netherlands

For any information about this medicine, please contact:

Merck Sharp & Dohme (UK) Limited

Tel: +44 (0) 208 154 8000

medicalinformationuk@msd.com

This leaflet was last revised in November 2021

This medicine has been given ‘conditional approval’. This means that there is more evidence to come about this medicine.

Other sources of information

www.molnupiravir.com/uk

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