AUTHORIZED FOR EMERGENCY USE IN THE TREATMENT OF COVID-19

- LAGEVRIO™ (molnupiravir) has not been approved, but has been authorized for emergency use by FDA under an Emergency Use Authorization (EUA), for the treatment of adults with mild-to-moderate COVID-19, who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate.

- The emergency use of LAGEVRIO is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Available Under Emergency Use Authorization

Lagevrio™
molnupiravir 200 mg capsules

Your doctor has prescribed LAGEVRIO. Read on to learn more.

Get started
Here, you'll learn more about LAGEVRIO, how to take it, and where you can fill a prescription for it. You can also find this information, and additional important safety information, in the fact sheet your doctor gave you when you were prescribed LAGEVRIO.

AUTHORIZED USE

- LAGEVRIO™ (molnupiravir) is an investigational medicine used to treat adults with mild-to-moderate COVID-19:
  - who are at risk for progression to severe COVID-19 including hospitalization or death, and for whom other COVID-19 treatment options approved or authorized by the FDA are not accessible or clinically appropriate.

- LAGEVRIO is not authorized:
  - For use in people less than 18 years of age
  - For prevention of COVID-19
  - For patients needing hospitalization for COVID-19
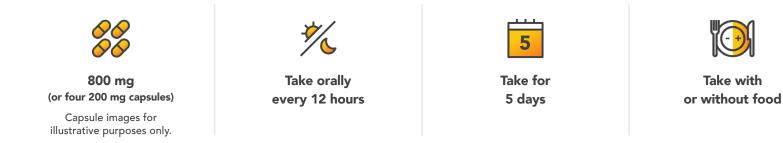 - For use for longer than 5 consecutive days

IMPORTANT SAFETY INFORMATION

- LAGEVRIO may cause harm to your unborn baby. It is not known if LAGEVRIO will harm your baby if you take LAGEVRIO during pregnancy. LAGEVRIO is not recommended for use in pregnancy and has not been studied in pregnancy.

- You and your healthcare provider may decide that you should take LAGEVRIO during pregnancy if there are no other COVID-19 treatment options approved or authorized by the FDA that are accessible or clinically appropriate for you. If you and your healthcare provider decide that you should take LAGEVRIO during pregnancy, you and your healthcare provider should discuss the known and potential benefits and the potential risks of taking LAGEVRIO during pregnancy.

Please see additional Important Safety Information continued below and review the **patient fact sheet** available on the website.

How do I take LAGEVRIO™ (molnupiravir)?

LAGEVRIO comes as a capsule. Take LAGEVRIO exactly as your doctor tells you to take it.

800 mg (or four 200 mg capsules) Capsule images for illustrative purposes only.	**Take orally every 12 hours**	**Take for 5 days**	**Take with or without food**

- Take 4 capsules of LAGEVRIO 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, even if you feel better.
- Take LAGEVRIO with or without food.
- You should stay in isolation for as long as your healthcare provider tells you to. Talk to your healthcare provider if you are not sure about how to properly isolate while you have COVID-19.
- **Swallow molnupiravir capsules whole. Do not open, break, or crush the capsules.** If you cannot swallow capsules whole, tell your doctor.

What do I do if I miss a dose of LAGEVRIO?

- 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

IMPORTANT SAFETY INFORMATION *(continued)*

- Individuals who are able to become pregnant should use a reliable method of birth control (contraception) correctly and consistently during treatment with LAGEVRIO and for 4 days after the last dose of LAGEVRIO. Talk to your healthcare provider about reliable birth control methods and tell your healthcare provider right away if you become pregnant or think you may have become pregnant during treatment with LAGEVRIO. Before starting treatment with LAGEVRIO your healthcare provider may do a pregnancy test to see if you are not pregnant.

- There is a pregnancy registry for individuals who take LAGEVRIO during pregnancy. The purpose of this program is to collect information about the health of you and your baby. If you are pregnant or become pregnant during treatment with LAGEVRIO, you are encouraged to report your use of LAGEVRIO during pregnancy to this pregnancy registry at https://covid-pr.pregistry.com or 1-800-616-3791.

Please see additional Important Safety Information continued below and review the **patient fact sheet** available on the website.

Lagevrio™
molnupiravir 200 mg capsules

AUTHORIZED USE

- LAGEVRIO™ (molnupiravir) is an investigational medicine used to treat adults with mild-to-moderate COVID-19:
    - who are at risk for progression to severe COVID-19 including hospitalization or death, and for whom other COVID-19 treatment options approved or authorized by the FDA are not accessible or clinically appropriate.

- LAGEVRIO is not authorized:
    - For use in people less than 18 years of age
    - For prevention of COVID-19
    - For patients needing hospitalization for COVID-19
    - For use for longer than 5 consecutive days

IMPORTANT SAFETY INFORMATION *(continued)*

- It is not known if LAGEVRIO can affect sperm. A reliable method of birth control (contraception) should be used consistently and correctly during treatment with LAGEVRIO and for at least 3 months after the last dose. The risk to sperm beyond 3 months is not known. Talk to your healthcare provider about reliable birth control methods or if you have questions or concerns about how LAGEVRIO may affect sperm.

- Before taking LAGEVRIO, tell your healthcare provider about all of your medical conditions including if you have any allergies, serious illnesses, or are pregnant or plan to become pregnant, are breastfeeding or plan to breastfeed.

- Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

- 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, or skin rash.

- The most common side effects of LAGEVRIO are diarrhea, nausea, and dizziness. These are not all the possible side effects of LAGEVRIO. Serious and unexpected side effects may happen. This medicine is still being studied, so it is possible that all of the risks are not known at this time. Contact your healthcare provider if you have any side effects that bother you or do not go away.

- Breastfeeding is not recommended during treatment with LAGEVRIO and for 4 days after the last dose of LAGEVRIO. If you are breastfeeding or plan to breastfeed, talk to your healthcare provider about your options and specific situation before taking LAGEVRIO.

- Take LAGEVRIO exactly as your healthcare provider tells you to take it. Take LAGEVRIO for 5 days. It is important that you complete the full 5 days of treatment with LAGEVRIO. Do not stop taking LAGEVRIO before you complete the full 5 days of treatment, even if you feel better.

- Contact your healthcare provider if you have any side effects that bother you or do not go away. Report side effects to FDA MedWatch at **www.fda.gov/medwatch** or call **1-800-FDA-1088 (1-800-332-1088)**.

Please read the accompanying <u>Fact Sheet for Patients and Caregivers</u> for LAGEVRIO™ (molnupiravir) and discuss it with your doctor. The <u>Fact Sheet for Healthcare Providers</u> also is available.

Please speak to your doctor if you have any additional questions about LAGEVRIO.

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Lagevrio™
molnupiravir 200 mg capsules