Patient Education

Molnupiravir FDA Fact Sheet

You must carefully read the "Consumer Information Use and Disclaimer" below in order to understand and correctly use this information

About this topic

Fact Sheet for Patients And Caregivers
Emergency Use Authorization (EUA) Of LAGEVRIO™ (molnupiravir) capsules For Coronavirus Disease 2019 (COVID-19)

What is the most important information I should know about LAGEVRIO?
LAGEVRIO may cause serious side effects, including:

- **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.
  - LAGEVRIO has not been studied in pregnancy. LAGEVRIO was studied in pregnant animals only. When LAGEVRIO was given to pregnant animals, LAGEVRIO caused harm to their unborn babies.
  - 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.

For individuals who are able to become pregnant:

- You should use a reliable method of birth control (contraception) consistently and correctly during treatment with LAGEVRIO and for 4 days after the last dose of LAGEVRIO. Talk to your healthcare provider about reliable birth control methods.
- Before starting treatment with LAGEVRIO your healthcare provider may do a pregnancy test to see if you are pregnant before starting treatment with LAGEVRIO.
- Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with LAGEVRIO.

Pregnancy Surveillance Program:

- There is a pregnancy surveillance program for individuals who take LAGEVRIO during pregnancy. The purpose of this program is to collect information about the health of you and your baby. Talk to your healthcare provider about how to take part in this program.
- If you take LAGEVRIO during pregnancy and you agree to participate in the pregnancy surveillance program and allow your healthcare provider to share your information with Merck Sharp & Dohme, then your healthcare provider will report your use of LAGEVRIO during pregnancy to Merck Sharp & Dohme LLC. by calling 1-877-888-4231 or pregnancyreporting.msd.com.

For individuals who are sexually active with partners who are able to become pregnant:

- It is not known if LAGEVRIO can affect sperm. While the risk is regarded as low, animal studies to fully assess the potential for LAGEVRIO to affect the babies of males treated with LAGEVRIO have not been completed. 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. Studies to understand the risk to sperm beyond 3 months are ongoing. Talk to your healthcare provider

about reliable birth control methods. Talk to your healthcare provider if you have questions or concerns about how LAGEVRIO may affect sperm.

You are being given this fact sheet because your healthcare provider believes it is necessary to provide you with LAGEVRIO for the treatment of adults with mild-to-moderate coronavirus disease 2019 (COVID-19) with positive results of direct SARS-CoV-2 viral testing, and who are at high 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.

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to make LAGEVRIO available during the COVID-19 pandemic (for more details about an EUA please see **"What is an Emergency Use Authorization?"** at the end of this document). LAGEVRIO is not an FDA-approved medicine in the United States. Read this Fact Sheet for information about LAGEVRIO. Talk to your healthcare provider about your options if you have any questions. It is your choice to take LAGEVRIO.

What is COVID-19?
COVID-19 is caused by a virus called a coronavirus. You can get COVID-19 through close contact with another person who has the virus.

COVID-19 illnesses have ranged from very mild-to-severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, serious illness 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 and diabetes, for example seem to be at higher risk of being hospitalized for COVID-19.

What is LAGEVRIO?
LAGEVRIO is an investigational medicine used to treat mild-to-moderate COVID-19 in adults:

- with positive results of direct SARS-CoV-2 viral testing, and
- who are at high 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.

The FDA has authorized the emergency use of LAGEVRIO for the treatment of mild-to-moderate COVID-19 in adults under an EUA. For more information on EUA, see the **"What is an Emergency Use Authorization (EUA)?"** section at the end of this Fact Sheet.

LAGEVRIO is not authorized:

- for use in people less than 18 years of age.
- for prevention of COVID-19.
- for people needing hospitalization for COVID-19.
- for use for longer than 5 consecutive days.

What should I tell my healthcare provider before I take LAGEVRIO?

Tell your healthcare provider if you:

- Have any allergies
- Are breastfeeding or plan to breastfeed
- Have any serious illnesses
- Are taking any medicines (prescription, over-the-counter, vitamins, or herbal products).

How do I take LAGEVRIO?

- Take LAGEVRIO exactly as your healthcare provider tells you to take it.
- 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 with LAGEVRIO. Do not stop taking LAGEVRIO before 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 LAGEVRIO capsules whole. Do not open, break, or crush the capsules. If you cannot swallow capsules whole, tell your healthcare provider.
- **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.

What are the important possible side effects of LAGEVRIO?

- See, **"What is the most important information I should know about LAGEVRIO?"**

- **Allergic Reactions.** 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

The most common side effects of LAGEVRIO are:

- diarrhea
- nausea
- dizziness

These are not all the possible side effects of LAGEVRIO. Not many people have taken 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.

What other treatment choices are there?

Veklury (remdesivir) is FDA-approved as an intravenous (IV) infusion for the treatment of mild-to-moderate COVID-19 in certain adults and children. Talk with your doctor to see if Veklury is appropriate for you.

Like LAGEVRIO, FDA may also allow for the emergency use of other medicines to treat people with COVID-19. Go to https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization for more information.

It is your choice to be treated or not to be treated with LAGEVRIO. Should you decide not to take it, it will not change your standard medical care.

What if I am breastfeeding?
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.

How do I report side effects with LAGEVRIO?
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).

How should I store LAGEVRIO?

- Store LAGEVRIO capsules at room temperature between 68°F to 77°F (20°C to 25°C).
- **Keep LAGEVRIO and all medicines out of the reach of children and pets.**

How can I learn more about COVID-19?

- Ask your healthcare provider.
- Visit www.cdc.gov/COVID19
- Contact your local or state public health department.
- Call Merck Sharp & Dohme at 1-800-672-6372 (toll free in the U.S.)
- Visit www.molnupiravir.com

What Is an Emergency Use Authorization (EUA)?

The United States FDA has made LAGEVRIO available under an emergency access mechanism called an Emergency Use Authorization (EUA) The EUA is supported by a Secretary of Health and Human Service (HHS) declaration that circumstances exist to justify emergency use of drugs and biological products during the COVID-19 pandemic.
LAGEVRIO for the treatment of mild-to-moderate COVID-19 in adults with positive results of direct SARS-CoV-2 viral testing, 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, has not undergone the same type of review as an FDA-approved product. In issuing an EUA under the COVID-19 public health emergency, the FDA has determined, among other things, that based on the total amount of scientific evidence available including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that the product may be effective for diagnosing, treating, or preventing COVID-19, or a serious or life-threatening disease or condition caused by COVID-19; that the known and potential benefits of the product, when used to diagnose, treat, or prevent such disease or condition, outweigh the known and potential risks of such product; and that there are no adequate, approved, and available alternatives.

All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic. The EUA for LAGEVRIO is in effect for the duration of the COVID-19 declaration justifying emergency use of LAGEVRIO, unless terminated or revoked (after which LAGEVRIO may no longer be used under the EUA).

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For patent information: www.msd.com/research/patent

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SOURCE: All content in this fact sheet was created and made available by the U.S. Food and Drug Administration (FDA), and may be electronically accessed at https://www.fda.gov/media/155055/download.

Molnupiravir FDA Fact Sheet: https://www.fda.gov/media/155055/download

Molnupiravir FDA Fact Sheet (spanish): https://www.fda.gov/media/155115/download

Additional information: http://www.msd.com/research/patent

Report side effects to FDA MedWatch: www.fda.gov/medwatch

Consumer Information Use and Disclaimer: We want you to understand more clearly each of the health conditions and procedures you may have. This patient leaflet is a summary of useful information to help you gain a better understanding of these health topics. Other information about this condition or procedure may be important for you to know. Please talk with your healthcare provider for more information about your special health needs.

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