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.**
  - o LAGEVRIO is not recommended for use in pregnancy.
  - o 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.
  - o 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.
  - o 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 Registry:
- 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.

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 a current diagnosis of mild-to-moderate coronavirus disease 2019 (COVID-19) 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 adults with a current diagnosis of mild to moderate COVID-19:
- 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
- take any medicines including prescription, over-the-counter medicines, vitamins, and 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.
- If your healthcare provider prescribes LAGEVRIO and tells you to take or give a dose through a nasogastric (NG) or orogastric (OG) tube, follow the instructions below: "**How to take or give a dose of LAGEVRIO through a nasogastric (NG) or orogastric (OG) feeding tube.**" You must have an NG or OG that is size 12 French (FR) or larger.
- **If you 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.

How to take or give a dose of LAGEVRIO through a nasogastric (NG) or orogastric (OG) feeding tube:

- Wash your hands well with soap and water.
- Gather the supplies you will need to take or give the prescribed dose of LAGEVRIO.
    - 4 LAGEVRIO capsules
    - 1 liquid measuring cup with mL markings to measure 40 mL of room temperature water
    - 1 clean container with a lid
    - 1 catheter tip syringe. Your healthcare provider should tell you what size catheter tip syringe you will need to take or give a dose of LAGEVRIO.
- Place the needed supplies on a clean work surface.
- Follow your healthcare provider's instructions on how to flush the NG or OG feeding tube. Flush the NG or OG feeding tube with **5 mL** of water before taking or giving a dose of LAGEVRIO.
- Carefully open 4 LAGEVRIO capsules, one at a time, and empty the contents into a clean container.
- Use the liquid measuring cup to measure 40 mL of room temperature water and add to the container containing the capsule contents.

- Place the lid on the container. Shake to mix the capsule contents and water well for **3 minutes**. **The capsule contents may not dissolve completely.**
- Remove the lid from the container and draw up all the LAGEVRIO and water mixture into a catheter tip syringe.
- Give all of the mixture right away through the NG or OG feeding tube. **Do not keep the mixture for future use**.
- **If any capsule contents are left in the container**:
  - Add 10 mL of water to the container, and mix to loosen any capsule contents that are left in the container.
  - Use the catheter tip syringe to draw up all of the mixture in the container.
  - Give the mixture through the NG or OG feeding tube.
  - Repeat this process as needed until you no longer see any capsule contents left in the container or catheter tip syringe.
- Use the same catheter tip syringe to flush the NG or OG feeding tube 2 times with 5 mL of water (10mL total).
- Rinse the container, lid and catheter tip syringe well with clean water after use. Place on a clean paper towel until next use.

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.**

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 adults with a current diagnosis of 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, 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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