Information about the Molnupiravir COVID-19 Treatment

On December 23, 2021, the FDA issued an Emergency Use Authorization for Ridgeback Biotherapeutics and Merk & Co.'s antiviral medication Molnupiravir (Lagevrio). Molnupiravir is an antiviral medication that is administered orally as a pill.[1] This authorization makes treatments available for emergency use. This fact sheet contains information about the molnupiravir antiviral treatment and is intended to help you make the most informed decision about receiving the treatment that may help reduce your risk of severe COVID-19 symptoms.

How does Molnupiravir work?

Molnupiravir is a medication that works by creating errors in the SARS-CoV-2 virus' genetic code and preventing the virus from further replicating. Molnupiravir is given immediately after testing positive for COVID-19.[1]

Who is Molnupiravir for?

Molnupiravir treats mild to moderate coronavirus disease (COVID-19) in adults with positive results of PCR testing, and who are at high risk of severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options authorized by the FDA are not accessible or clinically appropriate (see Figure 1). Molnupiravir is available by prescription only and should be initiated as soon as possible after diagnosis of COVID-19 and within three days of symptom onset.[1]

Molnupiravir is not authorized for the pre-exposure or post-exposure prevention of COVID-19 or for initiation of treatment in those requiring hospitalization due to severe or critical COVID-19. Molnupiravir is not a substitute for vaccination.[2]

Molnupiravir is not recommended[1]:

During pregnancy

- Molnupiravir may cause fetal harm. There is no available human data on the use of molnupiravir in pregnant individuals to evaluate the risk of major birth defects, miscarriage or adverse maternal or fetal outcomes.

While breastfeeding

- Molnupiravir may have potential for adverse reactions in infants. It is unknown whether molnupiravir effects infants via breastfeeding or milk production. It is recommended to abstain from breastfeeding until 4 days after the final dose.

Do not take molnupiravir if[1]:

- You are less than 18 years of age
- Molnupiravir may affect bone and cartilage growth in children. The safety and efficacy of molnupiravir have not been established in pediatric patients.

Figure 1: You are considered high-risk if you meet at least one of the following criteria[3]:

- Are 65 years of age or older
- Have a body mass index (BMI) equal to or over 25
- Are pregnant
- Have cancer
- Have a chronic kidney disease
- Have a chronic liver disease
- Have diabetes
- Have an immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Have a heart condition
- Have hypertension
- Have sickle cell disease
- Have a chronic lung disease such as
  - Chronic obstructive pulmonary disease
  - Moderate to severe asthma
  - Interstitial lung disease
  - Cystic fibrosis
  - Pulmonary hypertension
- Have a neurodevelopmental disorder such as cerebral palsy
- Have a mental health condition
- Have a medical-related technological dependence such as a tracheostomy or gastrostomy

This list does not include all medical conditions that place a person at higher risk of severe illness from COVID-19. It is important that you talk with your healthcare provider about your risk.

Though the risk is regarded as low, the potential of molnupiravir to affect the offspring of treated males is currently unknown. Studies that examine this risk have not been completed. The FDA recommends that sexually active individuals with partners of childbearing potential use a reliable method of contraception correctly and consistently during treatment and for at least 3 months after the last dose of molnupiravir[1].

No drug interactions have been identified based on the limited available data on the emergency use of molnupiravir authorized under this EUA.

How is Molnupiravir given?

Molnupiravir is administered as four pills taken orally twice daily for five days, for a total of 40 pills. Molnupiravir is not authorized for use for longer than five consecutive days.[2] Molnupiravir is a prescription-only medication to be initiated as soon as possible after diagnosis and within five days of symptom onset.[1]

What are the benefits of receiving Molnupiravir?

Benefits of treatment with Molnupiravir include[1]:

- Reduced risk of severe COVID-19 symptoms
- Reduced risk of hospitalization
- Reduced risk of death from COVID-19
- Oral treatment eliminates the time needed to receive the alternative infusion treatment in a medical setting, and treatment may be completed at home

What are the possible risks of receiving Molnupiravir?

Most common adverse reactions are diarrhea, nausea, and dizziness These have only occurred in less than 1% of patients.[1]

Molnupiravir is still being studied, so it is possible that all the risks are not known at this time.[4]

Is Molnupiravir safe?

In preclinical studies, molnupiravir did not show evidence of human DNA mutations.[1] The FDA has determined that it is reasonable to believe that molnupiravir may be effective for the treatment of mild-to-moderate COVID-19 in authorized patients. They also determined that the potential benefits of molnupiravir, when used consistent with the terms and conditions of the authorization, outweigh the potential risks of the product.[4] Molnupiravir is one of two authorized oral treatments for COVID-19.[5]

Where can I receive Molnupiravir treatment for COVID-19?

Molnupiravir may only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe anti-infective drugs.[1]

Resources

1. Fact Sheet for Healthcare Providers: Emergency Use Authorization for Molnupiravir. United States Food and Drug Administration. https://www.fda.gov/media/155054/download. Published December 23, 2021. Accessed January 25, 2022.
2. Coronavirus (COVID-19) Update: FDA Authorizes Additional Oral Antiviral for Treatment of COVID-19 in Certain Adults. United States Food and Drug Administration. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-oral-antiviral-treatment-covid-19-certain. Published December 23, 2021. Accessed January 26, 2022.
3. People with Certain Medical Conditions. U.S. Centers for Disease Control and Prevention. Accessed April 14, 2022. https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html
4. Fact Sheet for Patients, Parents, and Caregivers: Emergency Use Authorization (EUA) of Molnupiravir for Coronavirus Disease 2019 (COVID-19). United States Food and Drug Administration. https://www.fda.gov/media/155055/download. Published December 23, 2021. Accessed January 25, 2022.
5. Fact Sheet for Patients, Parents, and Caregivers: Emergency Use Authorization (EUA) of Paxlovid for Coronavirus Disease 2019 (COVID-19). United States Food and Drug Administration. https://www.fda.gov/media/155051/download. Published December 22, 2021. Accessed January 25, 2022.