Fact Sheet for Patients And Caregivers

Interim Authorization Of Molnupiravir For Coronavirus Disease 2019 (COVID-19)

What is the most important information I should know about molnupiravir?

Molnupiravir may cause serious side effects, including:

- **Molnupiravir may cause harm to your unborn baby. It is not known if molnupiravir will harm your baby if you take molnupiravir during pregnancy.**
  - Molnupiravir is not recommended for use in pregnancy.
  - Molnupiravir has not been studied in pregnancy. Molnupiravir was studied in pregnant animals only. When molnupiravir was given to pregnant animals, molnupiravir caused harm to their unborn babies.

For individuals who are able to become pregnant:

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

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

- It is not known if molnupiravir can affect sperm. While the risk is regarded as low, animal studies to fully assess the potential for molnupiravir to affect the babies of males treated with molnupiravir have not been completed. A reliable method of birth control (contraception) should be used consistently and correctly during treatment with molnupiravir 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 molnupiravir may affect sperm.

You are being given this fact sheet because your healthcare provider believes it is necessary to provide you with molnupiravir for the treatment of adults aged 18 years and above with mild-to-moderate coronavirus disease 2019 (COVID-19) who are at high risk for progressing to severe COVID-19 and/or hospitalization, and in whom alternative COVID-19 treatment options are not clinically appropriate.

Read this Fact Sheet for information about molnupiravir. Talk to your healthcare provider about your options if you have any questions. It is your choice to take molnupiravir.

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 molnupiravir?

Molnupiravir is used to treat mild-to-moderate COVID-19 in adults:

- aged 18 years and above who are at high risk for progressing to severe COVID-19 and/or hospitalization, and in whom alternative COVID-19 treatment options are not clinically appropriate.

Each molnupiravir capsule, for oral use, contains 200 mg of molnupiravir and the following inactive ingredients: croscarmellose sodium, hydroxypropyl cellulose, magnesium stearate and microcrystalline cellulose and purified water. The capsule shell is made of hypromellose, red iron oxide and titanium dioxide. The capsule is printed with white ink made of butyl alcohol,

dehydrated alcohol, isopropyl alcohol, potassium hydroxide, propylene glycol, purified water, shellac, strong ammonia solution and titanium dioxide.

Health Sciences Authority (HSA) has granted interim authorization of molnupiravir for the treatment of mild-to-moderate COVID-19 in adults under the Pandemic Special Access Route (PSAR). For more information on Interim Authorization, see the **"What is an Interim Authorization?"** section at the end of this Fact Sheet.

Molnupiravir 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 molnupiravir?

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 molnupiravir?

- Take molnupiravir exactly as your healthcare provider tells you to take it.
- Take 4 capsules of molnupiravir every 12 hours (for example, at 8 am and at 8 pm)
- **Take molnupiravir for 5 days**. It is important that you complete the full 5 days of treatment with molnupiravir. Do not stop taking molnupiravir before you complete the full 5 days of treatment, even if you feel better.
- Take molnupiravir 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 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 molnupiravir to make up for a missed dose.

What are the important possible side effects of molnupiravir?

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

- **Allergic Reactions.** Allergic reactions can happen in people taking molnupiravir, even after only 1 dose. Stop taking molnupiravir 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 molnupiravir are:

- diarrhea
- nausea
- dizziness

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

Like molnupiravir, HSA may allow for the emergency use of other medicines to treat people with COVID-19.

It is your choice to be treated or not to be treated with molnupiravir. 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 molnupiravir and for 4 days after the last dose of molnupiravir. If you are breastfeeding or plan to breastfeed, talk to your healthcare provider about your options and specific situation before taking molnupiravir.

How do I report side effects with molnupiravir?

Contact your healthcare provider if you have any side effects that bother you or do not go away.

How should I store molnupiravir?

- Store molnupiravir capsules at room temperature between 68°F to 77°F (20°C to 25°C).
- **Keep molnupiravir 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.
- Visit www.molnupiravir.com

What Is an Interim Authorization?

The HSA has made molnupiravir available under an emergency access mechanism called the Interim Authorization. The Interim Authorization enables regulatory agilities in responding to an emergency that may pose serious threats to the public such as in the situation of a pandemic. Given the urgent public health need, HSA will prioritize the review of emergency therapeutic products to facilitate timely access while ensuring the scientific rigor of the assessment of their quality, safety and efficacy.

Molnupiravir has not undergone the same type of review as an HSA-approved medicine. In issuing an Interim Authorization, the HSA must determine, among other things, that based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective for 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 treat or prevent such disease or condition, outweigh the known and potential risks of such product; and that there is on-going quality, safety and efficacy data generated to support the eventual transition of the Interim Authorization to product registration.

Product Owner:
Merck Sharp & Dohme LLC
126 East Lincoln Ave.
P.O. Box 2000
Rahway, New Jersey 07065
USA

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

Revised: October 2022