**COVID-19 Molnupiravir Oral Treatment**

**Educational Material and Consent Form**

Patient name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Facility name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of provider conducting informed consent\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Facts about the COVID-19 Emergency Use Authorization (EUA)**

Coronavirus is the virus that causes a disease called COVID-19. The virus is passed from person to person mostly by small droplets. These droplets come from the nose or mouth when an infected person coughs, sneezes, or speaks. Some people who are infected have no symptoms. Others have mild symptoms such as a cough and extreme tiredness. Other people have severe problems and may even die. COVID-19 has caused a worldwide pandemic.

The Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for Molnupiravir oral treatment. With an EUA, drugs are not reviewed in the same way as an FDA-approved or cleared product. The FDA may grant an EUA when certain standards are met, for instance, when there are no other choices for treating a health problem like COVID-19. The FDA issues EUAs based on scientific proof that shows the product is likely to be safe and effective.

Molnupiravir is for people with mild-to moderate symptoms of COVID-19 who:

* Have a positive COVID-19 test,
* Are 18 years and older,
* Are at high risk for severe COVID-19,
* Are not hospitalized due to COVID-19,
* Are not pregnant or breastfeeding, and
* Do not have access to other FDA-authorized treatment options.

**Risks and Common Problems**

There are risks linked to this treatment, which include but are not limited to:

**Allergic reaction:** All kinds of allergic reactions can happen; You could have a minor reaction, such as a rash, or a severe reaction, such as swelling of your lips, face, or throat; A severe allergic reaction is a medical emergency that can cause death.

**Diarrhea**

**Dizziness**

**Nausea**

All drugs can cause side effects. Problems that are not expected may happen. These problems may be life threatening. If you have any severe symptoms after the treatment, seek medical attention immediately.

**Other Choices**

If you decide not to take the treatment, then you may have other choices. The FDA may grant emergency use for other drugs to treat people with COVID-19. Your doctor may also talk with you about clinical studies you may be able to join.

**More Facts**

Molnupiravir should not be taken for more than five days.

Molnupiravir is not authorized for use as pre-exposure or as post-exposure prophylaxis for prevention of COVID-19.

After you get this treatment, you will still need to self-isolate per public health advice.

**Treatment of Pregnant or Lactating Women**

Molnupiravir is **NOT** recommended for patients who are:

* Pregnant or
* Breastfeeding

If there is a chance you may be pregnant, discuss with your provider about taking a pregnancy test before starting this drug.

If you could become pregnant, use a reliable method of birth control during treatment and **for at least three months after the last dose of Molnupiravir.**

Breastfeeding is not recommended during treatment and for 4 days after the last dose of Molnupiravir. Stop breastfeeding, pump, and discard breast milk during treatment and for 4 days after the last dose.

**Consent to Treatment**

This consent form told you about COVID-19 Molnupiravir oral treatment and its most common risks. If, after reviewing this form, you do not believe that you understand the risks and your choices, then **do not sign the form until all your questions have been answered.**

I have given my provider an updated medical history.

I understand the facts provided to me in this consent form, and it is my choice to receive COVID-19 Molnupiravir oral treatment. I give my consent for this treatment. By signing below, I agree that the staff/doctor has discussed the facts in this form with me, that no one has given me any guarantee about the treatment, that I have had a chance to ask questions, and that all my questions have been answered.

I agree I was given a copy of the oral treatment fact sheet today.

I have \_\_\_ no known drug allergies **or** \_\_\_ the drug allergies listed below:

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Signature of Patient or Responsible Party Date and Time

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Relationship to Patient (if Responsible Party is not Patient)

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Witness Date and Time

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Provider Date and Time