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Premium Healthcare Products

Fact Sheet for Patients, Parents and Caregivers
Emergency Use Authorization (EUA) of Molnarz™ (Molnupiravir Capsules 200 mg)
for Coronavirus Disease 2019 (COVID-19)

You are being given a medicine called **Molnarz™** (Molnupiravir Capsules 200 mg) for the treatment or post-exposure prevention of coronavirus disease 2019 (COVID-19). SARS-CoV-2 is the virus that causes COVID-19. This Fact Sheet contains information to help you understand the potential risks and potential benefits of taking **Molnarz™** (Molnupiravir Capsules 200 mg).

Molnupiravir is an unapproved drug that is authorized for use under this EUA. There are no approved, available products for the treatment of COVID-19 in adults who have mild-to-moderate COVID-19 and are at risk for progressing to severe COVID-19 and/or hospitalization. Other therapeutics are currently authorized for the same use as molnupiravir, such as monoclonal antibody therapies.

Receiving **Molnarz™** may help to treat COVID-19 in certain people.

Read this Fact Sheet for information about **Molnarz™**. Talk to your healthcare provider if you have questions. It is your choice if you receive **Molnarz™** or you may stop them at any time.

What is COVID-19?
COVID-19 is caused by a virus called a coronavirus, SARS-CoV-2. People can get COVID-19 through contact with another person who has the virus.

COVID-19 illnesses have ranged from very mild (including some with no reported symptoms) 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. People of all ages with severe, long-lasting (chronic) medical conditions like heart disease, lung disease, and diabetes, for example, and other conditions including obesity, seem to be at higher risk of being hospitalized for COVID-19. Older age, with or without other conditions, also places people at higher risk of being hospitalized for COVID-19.

What are the symptoms of COVID-19?
The symptoms of COVID-19 include fever, cough, and shortness of breath, which may appear 2 to 14 days after exposure. Serious illness including breathing problems can occur and may cause other medical conditions to become worse.

What is Molnarz™?
Molnarz contains the active substance molnupiravir. Molnarz™ is indicated for treatment of mildto moderate coronavirus disease 2019 (COVID-19) in adults 18 years old and above with a positive SARS-COV-2 diagnostic test and who are at risk for developing severe illness.

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Who should not take Molnarz™?

- if you are allergic to molnupiravir or any of the other ingredients of this medicine.
- do not use this medicine in children and adolescents aged less than 18 years. The use of molnupiravir in persons aged less than 18 years has not yet been studied.
- do not use this medicine in Hospitalized COVID-19 patients
- do not use this medicine in patients with anaemia
- do not use this medicine in patients with hepatitis B virus (HBV) or hepatitis C virus (HCV) with cirrhosis, endstage liver disease, hepatocellular carcinoma, aspartate aminotransferase (AST) and/or alanine aminotransferase (ALT) >3X upper limit of normal
- do not use this medicine in patients whose platelet count <100,000/µL or received a platelet transfusion within past 5 days
- do not use this medicine in patients with AIDS-defining illness in the past 6 months
- do not use this medicine in pregnant women

What should I tell the healthcare provider before I receive Molnarz™?
Tell the healthcare provider about all of your medical conditions, including:

- Have any allergies
- Have had a severe allergic reaction including anaphylaxis to Molnarz previously
- Have received a COVID-19 vaccine.
- Have any serious illnesses
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Are taking any medications (prescription, over-the-counter, vitamins, and herbal products)

How is Molnarz™ given?
Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

You should start Molnarz™ within 5 days of the onset of COVID-19 symptoms.
The recommended dose of Molnarz™ is four 200 mg capsules, every 12 hours for 5 days, as add on to standard of care treatment.
How to take:

- Swallow the capsule whole with plenty of fluid (for instance a glass of water)
- Do not open, break, or crush the capsules.
- This medicine can be taken with or without food.

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What are the important possible side effects of Molnarz™?
Possible side effects of Molnarz™ are:
Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common:

- headache
- diarrhoea
- catheter site pain
- nausea
- rhinorrhoea
- back pain
- feeling hot
- oropharyngeal pain
- somnolence
- rash
- pain in extremity
- feeling dizzy
- vomiting
- hives

What if I am pregnant or breastfeeding?
Animal studies with molnupiravir have shown harmful effects to the unborn animal. Molnarz™ is not recommended in pregnancy. Molnarz™ has not been studied in pregnancy and it is not known if Molnarz™ will harm your baby while you are pregnant.

If you are pregnant, think you may be pregnant, or are planning to have a baby, ask your doctor for advice. If you can become pregnant, you should use effective birth control while you are taking Molnarz™ and for 4 days after the last dose of Molnarz™.

If you are breast-feeding or are planning to breastfeed, tell your doctor before taking this medicine. Breast-feeding is not recommended during treatment and for 4 days after the last dose of Molnarz™. This is because it is not known if Molnarz™ gets into breast milk and will be passed to the baby.

How do I report side effects with Molnarz™?
Tell your healthcare provider right away if you have any side effect that bothers you or does not go away.

If you get any side effects talk to your doctor or pharmacist and report to the FDA at www.fda.gov.ph AND Faberco Life Sciences Inc. at safety@faberco.ph

This includes any possible side effects not listed in this leaflet.

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How can I learn more?

- Ask your healthcare provider
- Contact your local or state public health department

What is an Emergency Use Authorization (EUA)?

Emergency Use Authorization (EUA) is a regulatory mechanism to allow the use of medicines to prevent and/or reduce the impact of life-threatening diseases or conditions as caused by COVID-19. However, before grant of the EUA, rigorous assessments of laboratory and clinical trial data, including data on quality, safety, production of protective antibodies and efficacy is conducted. Safety is particularly critical aspect of this scrutiny and a risk-versus- benefit evaluation is done in the context of a public health emergency. Full licensure is obtained when the manufacturer submits the complete data. EUA by Philippines regulators is aligned with global guidelines.

Manufacturer:

Aurobindo Pharma Limited - Unit-III,
Survey No. 313 and 314,
Bachupally, Bachupally Mandal,
Medchal-Malkajgiri District,
Telangana State, India.

EUA Holder:

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