

### Evusheld Information for Patients, Parents, and Caregivers

Q: What is Evusheld?

- Evusheld is an investigational long-acting monoclonal antibody (mAb) therapy used to help prevent COVID-19 infection in certain high-risk individuals. It is a combination of two mAbs (tixagevimab and cilgavimab) that helps prevent COVID-19 infection by blocking a part of the spike protein of the SARS-CoV-2 virus.

Q: How is Evusheld administered?

- Evusheld is given as two injections at the same appointment. One shot is usually given in each buttock. At this time, Evusheld is a one-time dose.

Q: Who can receive Evusheld?

- Your healthcare provider will determine if Evusheld is an appropriate medication for you.
- Under the Emergency Use Authorization (EUA), Evusheld is authorized for use in
  - Adults and adolescents 12 years of age and older who weigh at least 88 pounds (40 kg),
    - Who are not currently infected with COVID-19 and have not had recent known close contact with an infected person
    - AND
    - Who may not mount an adequate immune response to COVID-19 vaccination because they have a weakened immune system due to a medical condition or immunosuppressive medicines or treatments OR
    - Who cannot get COVID-19 vaccine due to a documented history of severe adverse reaction to a COVID-19 vaccine and/or its ingredients.

Q: Who should NOT receive Evusheld?

- Under the Emergency Use Authorization (EUA), Evusheld is not authorized for use in individuals:
  - For treatment of COVID-19, or
  - For post-exposure prophylaxis of COVID-19 in individuals who have been exposed to someone infected with SARS-CoV-2.
- Evusheld should not be given to people who have had a severe allergic reaction to Evusheld or any of its ingredients.
- Evusheld is not a substitute for vaccination.

Q: What should I tell my healthcare provider before I receive EVUSHELD?

- Before taking Evusheld, discuss with your healthcare provider if you:
  - Have any allergies
  - Have low numbers of blood platelets (which help blood clotting), a bleeding disorder, or are taking blood thinning medications (to prevent blood clots)
  - Have had a heart attack or stroke, have other heart problems, or are at high risk of cardiac (heart) event
  - Are pregnant or plan to become pregnant
  - Are breastfeeding
  - Have any serious illness
  - Are taking any medications (prescription, over-the-counter, vitamins, or herbal products)

Q: What are the common side effects of Evusheld?

- As with all medications, Evusheld may cause side effects, most being mild to moderate. Headache, feeling tired, and cough were the most common side effects during clinical trials. Other possible side effects include pain, bruising or possible bleeding at the injection site, allergic reactions and cardiac (heart) events, which could be severe or life threatening.
- Talk to your healthcare provider about potential side effects and how to best manage them.

Q: Is Evusheld FDA Approved?

- Evusheld is not currently FDA approved. Evusheld is available under an Emergency Use Authorization (EUA) issued by the FDA. Under an EUA, the FDA has reviewed safety and effectiveness data ahead of full approval to make the product available quickly during a public health emergency, including the COVID-19 pandemic.

Q: Where can I learn more about Evusheld?

- The EUA Fact Sheet for Patients, Parents, or Caregivers as well as more information about EUAs can be found at these links:
  - <https://www.fda.gov/media/154702/download>
  - <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>

Q: Can I receive a COVID-19 vaccine after taking Evusheld?

- Evusheld is not a substitute for vaccination. All eligible individuals should receive a COVID-19 vaccination. However, it is recommended that individuals who have received a COVID-19 vaccine wait at least two weeks after vaccination before receiving Evusheld.

Q: Where is Evusheld available?

- Evusheld, like other COVID-19 treatments, is currently limited in supplies. Locations of publicly available COVID-19 Therapeutics can be found on the HealthData.gov website <https://healthdata.gov/Health/COVID-19-Public-Therapeutic-Locator/rxn6-qnx8/data>.

Q: How do I report side effects with Evusheld?

- 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](http://www.fda.gov/medwatch) or call 1-800-FDA-1088 (1-800-332-1088) or call AstraZeneca at 1-800-236-9933.

## **Paxlovid Information for Patients, Parents, and Caregivers**

Q: What is Paxlovid?

- Paxlovid is an investigational medicine used to treat mild-to-moderate COVID-19 in certain individuals at high-risk for progression to severe COVID-19, including hospitalization or death. Paxlovid is a combination of the nirmatrelvir, which disrupts viral multiplication in cells, and ritonavir, which helps boost the concentration of nirmatrelvir to therapeutic levels.

Q: How is Paxlovid taken?

- Paxlovid is available as a dose pack consisting of individual pink tablets of nirmatrelvir and white tablets of ritonavir.
- Two tablets of nirmatrelvir and 1 tablet of ritonavir are taken by mouth 2 times each day (morning and evening) for 5 days. The nirmatrelvir and ritonavir tablets should be taken at the same time.

- **Healthcare providers may recommend a lower dose for patients with kidney problems.**
- Tablets should be swallowed whole and may be taken with or without food.
- Do not stop taking Paxlovid without talking to your healthcare provider, even if you feel better.
- If you miss a dose of PAXLOVID within 8 hours of the time it is usually taken, take it as soon as you remember. If you miss a dose by more than 8 hours, skip the missed dose and take the next dose at your regular time. Do not take 2 doses of PAXLOVID at the same time.
  - If you take too much PAXLOVID, call your healthcare provider or go to the nearest hospital emergency room.
- If you are taking a ritonavir- or cobicistat-containing medicine to treat hepatitis C or Human Immunodeficiency Virus (HIV), you should continue to take your medicine as prescribed by your healthcare provider.

Q: Who can receive Paxlovid?

- Your healthcare provider will determine if Paxlovid is an appropriate medication for you.
- Under the Emergency Use Authorization (EUA), Paxlovid is authorized for use in adults and children 12 years of age and older who weigh at least 88 pounds (40 kg), who have tested positive for COVID-19 or first developed symptoms within the last 5 days, and who are at high risk for progression to severe COVID-19.

Q: Who should NOT receive Paxlovid?

- Patients who are allergic to any of the ingredients in Paxlovid.
- Patients who need to be admitted to the hospital for severe COVID-19.
- Paxlovid has significant interactions with many common medications that could cause serious or life-threatening side effects.
  - Paxlovid is not recommended for patients taking any of the following medicines:
    - Alfuzosin
    - Pethidine, piroxicam, propoxyphene
    - Ranolazine
    - Amiodarone, dronedarone, flecainide, propafenone, quinidine
    - Colchicine
    - Lurasidone, pimozone, clozapine
    - Dihydroergotamine, ergotamine, methylergonovine
    - Lovastatin, simvastatin
    - Sildenafil (Revatio®) for pulmonary arterial hypertension (PAH)
    - Triazolam, oral midazolam
    - Apalutamide
    - Carbamazepine, phenobarbital, phenytoin
    - Rifampin
    - St. John's Wort (hypericum perforatum)
  - These are not the only medicines that may cause serious side effects if taken with Paxlovid so tell your healthcare provider and pharmacist about all of the medicines you take, including prescriptions, over-the-counter medicines, vitamins and herbal supplements.
  - It is very important to tell your healthcare provider about all of the medicines you are taking because additional laboratory tests or changes in the dose of your other medicines may be necessary while you are taking Paxlovid. Your healthcare provider may also tell you about specific symptoms to watch out for that may indicate that you need to stop or decrease the dose of some of your other medicines.

Q: What should I tell my healthcare provider before I receive Paxlovid?

- Before taking Paxlovid, discuss with your healthcare provider if you:
  - Have any allergies
  - Have kidney or liver problems
  - Are pregnant or plan to become pregnant
  - Are breastfeeding
  - Are taking oral contraceptives
  - Have any serious illnesses or medical history

Q: What are the common side effects of Paxlovid?

- As with all medications, Paxlovid may cause side effects, most being mild to moderate. Diarrhea, high blood pressure, muscle aches, and altered sense of taste were the most common side effects during clinical trials.
- Other possible side effects of Paxlovid include:
  - Liver Problems.
    - Tell your healthcare provider right away if you have any of these signs and symptoms of liver problems: loss of appetite, yellowing of your skin and the whites of eyes (jaundice), dark-colored urine, pale colored stools and itchy skin, stomach area (abdominal) pain.
  - Resistance to HIV Medicines.
    - If you have untreated HIV infection, PAXLOVID may lead to some HIV medicines not working as well in the future.
- Paxlovid may affect how your birth control pills work. Females who are able to become pregnant should use another effective alternative form of contraception or an additional barrier method of contraception. Talk to your healthcare provider if you have any questions about contraceptive methods that might be right for you.

Q: Is Paxlovid FDA Approved?

- Paxlovid is not currently FDA approved. Paxlovid is available under an Emergency Use Authorization (EUA) issued by the FDA. Under an EUA, the FDA has reviewed safety and effectiveness data ahead of full approval to make the product available quickly during a public health emergency, including the COVID-19 pandemic.

Q: Where can I learn more about Paxlovid?

- The EUA Fact Sheet for Patients, Parents, or Caregivers as well as more information about EUAs can be found at these links:
  - <https://www.fda.gov/media/155051/download>
  - <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>

Q: Where is Paxlovid available?

- Paxlovid, like other COVID-19 treatments, is currently limited in supplies. Locations of publicly available COVID-19 Therapeutics can be found on the HealthData.gov website (<https://healthdata.gov/Health/COVID-19-Public-Therapeutic-Locator/rxn6-qnx8/data>).

Q: How do I report side effects with Paxlovid?

- 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](http://www.fda.gov/medwatch) or call 1-800-FDA-1088 (1- 800-332-1088) or you can report side effects to Pfizer Inc. at the website <https://www.pfizersafetyreporting.com> or call 1-800-438-1985 or fax 1-866-635-8337



## Molnupiravir Information for Patients, Parents, and Caregivers

### Q: What is Molnupiravir?

- Molnupiravir is an investigational medicine used to treat mild-to-moderate COVID-19 in individuals at high-risk for progression to severe COVID-19, including hospitalization or death. Molnupiravir works by blocking viral replication inside cells.

### Q: How is Molnupiravir taken?

- Four capsules of Molnupiravir are taken by mouth every 12 hours (morning and evening) for 5 days
- Tablets should be swallowed whole and may be taken with or without food.
- Do not stop taking Molnupiravir without talking to your healthcare provider, even if you feel better.
- If you miss a dose of Molnupiravir within 10 hours of the time it is usually taken, take it as soon as you remember. If you miss a dose by more than 10 hours, skip the missed dose and take the next dose at your regular time. Do not take 2 doses of Molnupiravir at the same time.
  - If you take too much Molnupiravir, call your healthcare provider or go to the nearest hospital emergency room right away.
- For women who are able to become pregnant:
  - Use a reliable method of birth control (contraception) during treatment with Molnupiravir and for 4 days after the last dose.
  - Individuals with partners who may become pregnant should use effective contraception during their partner's treatment and for at least 3 months after the last dose of Molnupiravir.

### Q: Who can receive Molnupiravir?

- Your healthcare provider will determine if Molnupiravir is an appropriate medication for you.
- Under the Emergency Use Authorization (EUA), Molnupiravir is authorized for use in adults 18 years of age and older who have tested positive for COVID-19 or first developed symptoms within the last 5 days, who are at high risk for progression to severe COVID-19, and for whom other COVID-19 treatment options authorized by the FDA are not accessible or clinically appropriate.

### Q: Who should NOT receive Molnupiravir?

- Patients who are allergic to any of the ingredients in Molnupiravir.
- Patients who need hospitalization for COVID-19.
- Patients who are pregnant.
  - Molnupiravir has not been studied in pregnancy. Based on animal studies, Molnupiravir could cause harm to an unborn baby.
  - Molnupiravir is not recommended for use in pregnancy.
  - **Merck's Pregnancy Surveillance Program:**
    - There is a pregnancy surveillance program for women who take Molnupiravir during pregnancy. Talk to your healthcare provider about how to take part in this program.
    - If you take Molnupiravir during pregnancy and you agree to participate in the pregnancy surveillance program and allow your healthcare provider to share your information with Merck Sharp & Dohme, then your healthcare provider will report your use of Molnupiravir during pregnancy to Merck Sharp & Dohme Corp. by calling 1-877-888-4231 or [pregnancyreporting.msdc.com](https://www.merck.com/medwatch/pregnancyreporting.msdc.com).
  - Before starting Molnupiravir, your healthcare provider may do a pregnancy test.
- Breastfeeding is not recommended during treatment with Molnupiravir and for 4 days after the last dose.
- Additionally, before taking Molnupiravir, discuss with your healthcare provider if you:

- Have any allergies
- Have any serious illnesses
- Taking any medicines (prescription, over-the-counter, vitamins, or herbal products)

Q: What are the common side effects of Molnupiravir?

- As with all medications, Molnupiravir may cause side effects, most being mild to moderate. Diarrhea, nausea, and dizziness were the most common side effects during clinical trials.

Q: Is Molnupiravir FDA Approved?

- Molnupiravir is not currently FDA approved. Molnupiravir is available under an Emergency Use Authorization (EUA) issued by the FDA. Under an EUA, the FDA has reviewed safety and effectiveness data ahead of full approval to make the product available quickly during a public health emergency, including the COVID-19 pandemic.

Q: Where can I learn more about Molnupiravir?

- The EUA Fact Sheet for Patients, Parents, or Caregivers as well as more information about EUAs can be found at these links:
  - <https://www.fda.gov/media/155055/download>
  - <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>

Q: Where is Molnupiravir available?

- Molnupiravir, like other COVID-19 treatments, is currently limited in supplies. Locations of publicly available COVID-19 Therapeutics can be found on the HealthData.gov website (<https://healthdata.gov/Health/COVID-19-Public-Therapeutic-Locator/rxn6-qnx8/data>).

Q: 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.
- Report side effects to FDA MedWatch at [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088 (1-800-332-1088).