

# COVID Oral Antivirals MMC Guide

## Is The Patient Eligible For Oral Antivirals

≥12 years old, Weight ≥40 kg  
Positive SARS-CoV-2 Test  
Symptoms for ≤5 days  
High risk for progression to severe disease  
Does not require hospitalization for COVID

## Does The Patient Have A Paxlovid Contraindication

Hypersensitivity to nirmatrelvir or ritonavir  
On contraindicating medication (see box)  
Severe renal impairment (eGFR <30 mL/min)  
Severe hepatic impairment (Child-Pugh Class C)

Labs not required unless suspicion for renal or hepatic disease

If moderate renal impairment, use renal dosing

## Contraindicated Medications

Alfuzosin (Uroxatral)	Lovastatin (Altoprev)	Propoxyphene
Amiodarone	Lurasidone (Latuda)	Quinidine
Apalutamide (Erleada)	Methylergonovine (Methergine)	Ranolazine (Ranexa)
Carbamazepine (Tegretol)	Midazolam (Versed)	Rifampin
Colchicine	Pethidine (Meperidine, Demerol)	Sildenafil (Viagra, Revatio)
Clozapine (Clozaril)	Phenobarbital (Luminal)	Simvastatin (Zocor)
Dihydroergotamine (DHE)	Phenytoin (Dilantin)	St. John's Wort (Herbal)
Dronedarone (Multaq)	Pimozide (Orap)	Triazolam (Halcion)
Ergotamine (Ergomar)	Piroxicam (Feldene)	
Flecainide (Tambocor)	Propafenone (Rythmol)	

SCM will **not** alert you to contraindicated or warning meds

If patient meets criteria for both medications, **prescribe both** and on molnupiravir Rx, add free text, "To be used in case Paxlovid prescription cannot be filled because of supply limitation"

The list of medications that are not contraindicating but for which there are warnings is extensive and includes warfarin, rivaroxaban, quetiapine, calcium channel blockers, digoxin, statins, ethinyl estradiol, cyclosporine, tacrolimus, sirolimus, methadone, corticosteroids, and many others. See EUA.

Enter the prescription via Prescription Writer > favorites > COVID-19 Oral Antiviral Treatment

No need to populate fields with blue star

Additional free text that must be added to both Rx:

- Patient's phone number and address
- Date of symptom onset
- Ethnicity (non-white race is considered a high risk feature)

Prescription must be e-Prescribed to **Alto Pharmacy**, zip code 10017

Patient should go home and isolate. Patient will receive call or text message from Alto pharmacy that they must respond to, after which Alto will **deliver prescription** if meds available and patient deemed by pharmacy to meet DOH criteria

Patient should contact Alto Pharmacy with further questions: 800.874.5881

Counsel patient that adverse drug reactions are presently unknown, and that if any untoward reaction is experienced, it should be reported to FDA Medwatch Program [fda.gov/medwatch](https://www.fda.gov/medwatch)

Print 2 copies of EUA consent for both drugs (if both prescribed)  
One for patient, one signed and scanned into chart

Patient must be discharged with patient information sheet and copy of EUA consent for both drugs (if both prescribed)

## Does The Patient Have A Molnupiravir Warning

**Age <18:** not authorized for patients under 18

**Pregnancy:** evidence of teratogenicity in animal studies

If breastfeeding, not recommended during and until 4 days after conclusion of treatment

Males of reproductive potential who are sexually active with females of childbearing potential should use a reliable method of contraception correctly and consistently during treatment and for at least **3 months** after the last dose

## Paxlovid Rx

300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet), with all three tablets taken together twice daily for 5 days

### if moderate renal impairment (eGFR 30-60 mL/min)

150 mg nirmatrelvir (one 150 mg tablet) with 100 mg ritonavir (one 100 mg tablet), with both tablets taken together twice daily for 5 days

## Molnupiravir Rx

800 mg (four 200 mg capsules) taken orally every 12 hours for 5 days

## **Patient Consent to Paxlovid (Nirmatrelvir/Ritonavir) Treatment for COVID-19**

Your physician is recommending that you receive Paxlovid for treatment of coronavirus disease 2019 (COVID-19).

**Paxlovid is an investigational medication, meaning that the U.S. Food and Drug Administration (FDA) has not yet approved the medication for general use. However, FDA has authorized the emergency use of Paxlovid under an Emergency Use Authorization (EUA) for certain patients.**

*Please read the following information carefully before signing this form. It provides important details about the use of Paxlovid, as well as the risks and possible benefits of using it.*

### **Information about the Treatment**

#### **What is Paxlovid and why is it being recommended?**

Nirmatrelvir is a SARS-CoV-2 main protease inhibitor and ritonavir is an HIV-1 protease inhibitor and CYP3A inhibitor used to treat mild-to-moderate COVID-19 in adults and children [12 years of age and older weighing at least 88 pounds (40 kg)] with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

#### **What can I expect when receiving this treatment?**

You will be given nirmatrelvir tablets co-packaged with ritonavir tablets. You will swallow tablets whole by mouth with or without food. The treatment is taken two times each day for five days. Do not chew, break, or crush the tablets.

#### **What other treatments are available?**

Like Paxlovid, FDA may allow for the emergency use of other medicines to treat people with COVID-19. You should discuss all available treatment options with your physician.

#### **What are the possible risks of receiving Paxlovid?**

Possible side effects of Paxlovid include allergic reactions. Signs and symptoms may include: fever, chills, low blood pressure, changes in your heartbeat, shortness of breath, wheezing, swelling of your lips, face, or throat, rash including hives, itching, headache, nausea, vomiting, sweating, muscle aches, dizziness and shivering. Other possible side effects of Paxlovid include liver problems, resistance to HIV medicines, altered sense of taste, diarrhea, high blood pressure, and muscle aches. These are not all the possible side effects of Paxlovid. You may have other side effects that are not known at this time and may include serious injury or pain, disability, or death. Report side effects to Paxlovid to your healthcare provider and FDA Medwatch or to Pfizer, Inc as outlined in the *Fact Sheet for Patients, Parents and Caregivers: Emergency Use Authorization (EUA) of Paxlovid for Coronavirus Disease 2019 (COVID-19)*. You should tell your healthcare provider if you have any allergies, have liver or kidney disease, are pregnant or plan to be pregnant, are breastfeeding a child, have any serious illnesses, or take any medications including prescription and over-the-counter medicines, vitamins, and herbal supplements. Do not start taking a new medicine without telling your healthcare provider.

#### **What are the possible benefits of receiving Paxlovid?**

The expected benefit is a reduction in the likelihood that your COVID-19 symptoms progress from mild or moderate to severe, including hospitalization or death. However, it is uncertain whether Paxlovid will be an effective treatment for COVID-19, and you might not experience any benefit.

**Can I change my mind after I sign this form?**

Yes, your treatment is fully voluntary and you are free to not proceed with, or stop, treatment at any time. Your choice will not affect the care that you are receiving at Maimonides Medical Center.

**What if I am pregnant or breastfeeding?**

There is no experience treating pregnant women or breastfeeding mothers with Paxlovid. For a mother and unborn baby, the benefit of taking Paxlovid may be greater than the risk from the treatment. If you are pregnant, discuss your options and specific situation with your healthcare provider. It is recommended that you use effective barrier contraception or do not have sexual activity while taking Paxlovid. If you are breastfeeding, discuss your options and specific situation with your healthcare provider.

**Consent to Receive Paxlovid**

By signing this informed consent document, I am agreeing to receive Paxlovid. I have discussed with my physician the risks and benefits associated with the administration of Paxlovid, and my physician has also informed me of alternatives to receiving Paxlovid. I understand that Paxlovid is not yet approved by FDA for treating COVID-19. I also understand that Paxlovid are still under investigation. Therefore, there may be risks, side effects, and/or long-term effects that are related to this treatment but are unknown at this time.

I acknowledge that I have been provided a copy of this informed consent document and the *Fact Sheet for Patients, Parents and Caregivers: Emergency Use Authorization (EUA) of Paxlovid for Coronavirus Disease 2019 (COVID-19)* (Fact Sheet). I acknowledge that I have had an opportunity to read the Fact Sheet provided to me and have had an opportunity to discuss the same with my physician.

I agree that I have read this form or have had it read to me and I have had any questions or concerns that I have regarding the administration or purpose of Paxlovid fully and adequately explained to me. By signing below, I acknowledge and consent to the administration of Paxlovid for the treatment of my COVID-19 illness knowing the risks associated with the emergency use of this drug.

\_\_\_\_\_  
Printed Name of Patient

\_\_\_\_\_  
Signature (Patient or Authorized Representative) Date

**Consenting Provider**

I have explained the treatment to the patient/authorized representative, including the risks, benefits, and alternatives, and have answered all questions about this treatment to the best of my ability.

\_\_\_\_\_  
Printed Name

\_\_\_\_\_  
Signature Date and Time

*Where applicable:*

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Interpreter Signature and Language Used Date and Time

## **Patient Consent to Paxlovid (Nirmatrelvir/Ritonavir) Treatment for COVID-19**

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*Please read the following information carefully before signing this form. It provides important details about the use of Paxlovid, as well as the risks and possible benefits of using it.*

### **Information about the Treatment**

#### **What is Paxlovid and why is it being recommended?**

Nirmatrelvir is a SARS-CoV-2 main protease inhibitor and ritonavir is an HIV-1 protease inhibitor and CYP3A inhibitor used to treat mild-to-moderate COVID-19 in adults and children [12 years of age and older weighing at least 88 pounds (40 kg)] with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

#### **What can I expect when receiving this treatment?**

You will be given nirmatrelvir tablets co-packaged with ritonavir tablets. You will swallow tablets whole by mouth with or without food. The treatment is taken two times each day for five days. Do not chew, break, or crush the tablets.

#### **What other treatments are available?**

Like Paxlovid, FDA may allow for the emergency use of other medicines to treat people with COVID-19. You should discuss all available treatment options with your physician.

#### **What are the possible risks of receiving Paxlovid?**

Possible side effects of Paxlovid include allergic reactions. Signs and symptoms may include: fever, chills, low blood pressure, changes in your heartbeat, shortness of breath, wheezing, swelling of your lips, face, or throat, rash including hives, itching, headache, nausea, vomiting, sweating, muscle aches, dizziness and shivering. Other possible side effects of Paxlovid include liver problems, resistance to HIV medicines, altered sense of taste, diarrhea, high blood pressure, and muscle aches. These are not all the possible side effects of Paxlovid. You may have other side effects that are not known at this time and may include serious injury or pain, disability, or death. Report side effects to Paxlovid to your healthcare provider and FDA Medwatch or to Pfizer, Inc as outlined in the *Fact Sheet for Patients, Parents and Caregivers: Emergency Use Authorization (EUA) of Paxlovid for Coronavirus Disease 2019 (COVID-19)*. You should tell your healthcare provider if you have any allergies, have liver or kidney disease, are pregnant or plan to be pregnant, are breastfeeding a child, have any serious illnesses, or take any medications including prescription and over-the-counter medicines, vitamins, and herbal supplements. Do not start taking a new medicine without telling your healthcare provider.

#### **What are the possible benefits of receiving Paxlovid?**

The expected benefit is a reduction in the likelihood that your COVID-19 symptoms progress from mild or moderate to severe, including hospitalization or death. However, it is uncertain whether Paxlovid will be an effective treatment for COVID-19, and you might not experience any benefit.

**Can I change my mind after I sign this form?**

Yes, your treatment is fully voluntary and you are free to not proceed with, or stop, treatment at any time. Your choice will not affect the care that you are receiving at Maimonides Medical Center.

**What if I am pregnant or breastfeeding?**

There is no experience treating pregnant women or breastfeeding mothers with Paxlovid. For a mother and unborn baby, the benefit of taking Paxlovid may be greater than the risk from the treatment. If you are pregnant, discuss your options and specific situation with your healthcare provider. It is recommended that you use effective barrier contraception or do not have sexual activity while taking Paxlovid. If you are breastfeeding, discuss your options and specific situation with your healthcare provider.

**Consent to Receive Paxlovid**

By signing this informed consent document, I am agreeing to receive Paxlovid. I have discussed with my physician the risks and benefits associated with the administration of Paxlovid, and my physician has also informed me of alternatives to receiving Paxlovid. I understand that Paxlovid is not yet approved by FDA for treating COVID-19. I also understand that Paxlovid are still under investigation. Therefore, there may be risks, side effects, and/or long-term effects that are related to this treatment but are unknown at this time.

I acknowledge that I have been provided a copy of this informed consent document and the *Fact Sheet for Patients, Parents and Caregivers: Emergency Use Authorization (EUA) of Paxlovid for Coronavirus Disease 2019 (COVID-19)* (Fact Sheet). I acknowledge that I have had an opportunity to read the Fact Sheet provided to me and have had an opportunity to discuss the same with my physician.

I agree that I have read this form or have had it read to me and I have had any questions or concerns that I have regarding the administration or purpose of Paxlovid fully and adequately explained to me. By signing below, I acknowledge and consent to the administration of Paxlovid for the treatment of my COVID-19 illness knowing the risks associated with the emergency use of this drug.

\_\_\_\_\_  
Printed Name of Patient

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Signature (Patient or Authorized Representative) Date

**Consenting Provider**

I have explained the treatment to the patient/authorized representative, including the risks, benefits, and alternatives, and have answered all questions about this treatment to the best of my ability.

\_\_\_\_\_  
Printed Name

\_\_\_\_\_  
Signature Date and Time

*Where applicable:*

\_\_\_\_\_  
Interpreter Signature and Language Used Date and Time

## Patient Consent to Molnupiravir Treatment for COVID-19

Your physician is recommending that you receive molnupiravir for treatment of coronavirus disease 2019 (COVID-19).

**Molnupiravir is an investigational medication, meaning that the U.S. Food and Drug Administration (FDA) has not yet approved the medication for general use. However, FDA has authorized the emergency use of molnupiravir under an Emergency Use Authorization (EUA) for certain patients.**

*Please read the following information carefully before signing this form. It provides important details about the use of molnupiravir, as well as the risks and possible benefits of using it.*

### Information about the Treatment

#### What is molnupiravir and why is it being recommended?

Molnupiravir is a cytidine nucleoside analogue that inhibits SARS-CoV-2 replication. It is used to treat mild-to-moderate COVID-19 in adults 18 years of age and older with positive results of direct SARS-CoV-2 viral testing, who are at high risk for progression to severe COVID-19 including hospitalization or death, and for whom alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate.

#### What can I expect when receiving this treatment?

You will be given molnupiravir 200 mg capsules. The treatment is 800 mg (four 200 mg capsules) swallowed whole by mouth every 12 hours (for example, at 8 am and at 8 pm) for five days, with or without food. Do not open, break, or crush the capsules.

#### What other treatments are available?

Like molnupiravir, FDA may allow for the emergency use of other medicines to treat people with COVID-19. You should discuss all available treatment options with your physician.

#### What are the possible risks of receiving molnupiravir?

Possible side effects of molnupiravir include allergic reactions. Signs and symptoms may include: fever, chills, low blood pressure, changes in your heartbeat, shortness of breath, wheezing, swelling of your lips, face, or throat, rash including hives, itching, headache, nausea, vomiting, sweating, muscle aches, dizziness and shivering. Other possible side effects of molnupiravir include harm to your unborn baby, diarrhea, nausea, and dizziness. These are not all the possible side effects of molnupiravir. You may have other side effects that are not known at this time and may include serious injury or pain, disability, or death. Report side effects to molnupiravir to your healthcare provider and FDA Medwatch or to Pfizer, Inc as outlined in the *Fact Sheet for Patients, Parents and Caregivers: Emergency Use Authorization (EUA) of Molnupiravir for Coronavirus Disease 2019 (COVID-19)*. You should tell your healthcare provider if you have any allergies, are pregnant or plan to be pregnant, are breastfeeding or plan to breastfeed, have any serious illnesses, or take any medications including prescription and over-the-counter medicines, vitamins, and herbal supplements.

#### What are the possible benefits of receiving molnupiravir?

The expected benefit is a reduction in the likelihood that your COVID-19 symptoms progress from mild or moderate to severe, including hospitalization or death. However, it is uncertain whether molnupiravir will be an effective treatment for COVID-19, and you might not experience any benefit.

#### Can I change my mind after I sign this form?

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**What if I am pregnant or breastfeeding? What if I am able to become pregnant or are sexually active with partners who are able to become pregnant?**

Molnupiravir is not recommended for use in pregnancy. Molnupiravir may cause harm to your unborn baby. Molnupiravir has not been studied in human pregnancy. When molnupiravir was given to pregnant animals, molnupiravir caused harm to their unborn babies. If you are pregnant, you and your healthcare provider should discuss the known and potential benefits and the potential risks of taking molnupiravir during pregnancy. 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.

If you are able to be 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. It is not known if molnupiravir can affect sperm. If you are an individual who is sexually active with partners who are able to become pregnant, 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.

**Consent to Receive Molnupiravir**

By signing this informed consent document, I am agreeing to receive molnupiravir. I have discussed with my physician the risks and benefits associated with the administration of molnupiravir, and my physician has also informed me of alternatives to receiving molnupiravir. I understand that molnupiravir is not yet approved by FDA for treating COVID-19. I also understand that molnupiravir are still under investigation. Therefore, there may be risks, side effects, and/or long-term effects that are related to this treatment but are unknown at this time.

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Printed Name of Patient

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Signature (Patient or Authorized Representative) Date

**Consenting Provider**

I have explained the treatment to the patient/authorized representative, including the risks, benefits, and alternatives, and have answered all questions about this treatment to the best of my ability.

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Printed Name

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Signature Date and Time

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#### What can I expect when receiving this treatment?

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#### What other treatments are available?

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#### What are the possible risks of receiving molnupiravir?

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#### What are the possible benefits of receiving molnupiravir?

The expected benefit is a reduction in the likelihood that your COVID-19 symptoms progress from mild or moderate to severe, including hospitalization or death. However, it is uncertain whether molnupiravir will be an effective treatment for COVID-19, and you might not experience any benefit.

#### Can I change my mind after I sign this form?

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**What if I am pregnant or breastfeeding? What if I am able to become pregnant or are sexually active with partners who are able to become pregnant?**

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If you are able to be 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. It is not known if molnupiravir can affect sperm. If you are an individual who is sexually active with partners who are able to become pregnant, 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.

**Consent to Receive Molnupiravir**

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I agree that I have read this form or have had it read to me and I have had any questions or concerns that I have regarding the administration or purpose of molnupiravir fully and adequately explained to me. By signing below, I acknowledge and consent to the administration of molnupiravir for the treatment of my COVID-19 illness knowing the risks associated with the emergency use of this drug.

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Printed Name of Patient

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Signature (Patient or Authorized Representative) Date

**Consenting Provider**

I have explained the treatment to the patient/authorized representative, including the risks, benefits, and alternatives, and have answered all questions about this treatment to the best of my ability.

\_\_\_\_\_  
Printed Name

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Signature Date and Time

*Where applicable:*

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Interpreter Signature and Language Used Date and Time

## **FACT SHEET FOR PATIENTS, PARENTS, AND CAREGIVERS**

### **EMERGENCY USE AUTHORIZATION (EUA) OF PAXLOVID FOR CORONAVIRUS DISEASE 2019 (COVID-19)**

You are being given this Fact Sheet because your healthcare provider believes it is necessary to provide you with PAXLOVID for the treatment of mild-to-moderate coronavirus disease (COVID-19) caused by the SARS-CoV-2 virus. This Fact Sheet contains information to help you understand the risks and benefits of taking the PAXLOVID you have received or may receive.

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to make PAXLOVID available during the COVID-19 pandemic (for more details about an EUA please see “**What is an Emergency Use Authorization?**” at the end of this document). PAXLOVID is not an FDA-approved medicine in the United States. Read this Fact Sheet for information about PAXLOVID. Talk to your healthcare provider about your options or if you have any questions. It is your choice to take PAXLOVID.

#### **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 PAXLOVID?**

PAXLOVID is an investigational medicine used to treat mild-to-moderate COVID-19 in adults and children [12 years of age and older weighing at least 88 pounds (40 kg)] with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death. PAXLOVID is investigational because it is still being studied. There is limited information about the safety and effectiveness of using PAXLOVID to treat people with mild-to-moderate COVID-19.

The FDA has authorized the emergency use of PAXLOVID for the treatment of mild-to-moderate COVID-19 in adults and children [12 years of age and older weighing at least 88 pounds (40 kg)] with a positive test for the virus that causes COVID-19, and who are at high risk for progression to severe COVID-19, including hospitalization or death, under an EUA.

## What should I tell my healthcare provider before I take PAXLOVID?

### Tell your healthcare provider if you:

- Have any allergies
- Have liver or kidney disease
- Are pregnant or plan to become pregnant
- Are breastfeeding a child
- Have any serious illnesses

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Some medicines may interact with PAXLOVID and may cause serious side effects. Keep a list of your medicines to show your healthcare provider and pharmacist when you get a new medicine.

You can ask your healthcare provider or pharmacist for a list of medicines that interact with PAXLOVID. **Do not start taking a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take PAXLOVID with other medicines.

### **Tell your healthcare provider if you are taking combined hormonal contraceptive.**

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.

### How do I take PAXLOVID?

- PAXLOVID consists of 2 medicines: nirmatrelvir and ritonavir.
  - Take 2 pink tablets of nirmatrelvir with 1 white tablet of ritonavir by mouth 2 times each day (in the morning and in the evening) for 5 days. **For each dose, take all 3 tablets at the same time.**
  - **If you have kidney disease, talk to your healthcare provider. You may need a different dose.**
- Swallow the tablets whole. Do not chew, break, or crush the tablets.
- Take PAXLOVID 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 right away.
- 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.

Talk to your healthcare provider if you do not feel better or if you feel worse after 5 days.

## Who should generally not take PAXLOVID?

### Do not take PAXLOVID if:

- You are allergic to nirmatrelvir, ritonavir, or any of the ingredients in PAXLOVID.
- You are 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*)

Taking PAXLOVID with these medicines may cause serious or life-threatening side effects or affect how PAXLOVID works.

These are not the only medicines that may cause serious side effects if taken with PAXLOVID. PAXLOVID may increase or decrease the levels of multiple other medicines. 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.

## What are the important possible side effects of PAXLOVID?

### Possible side effects of PAXLOVID are:

- **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.

- **Other possible side effects include:**

- altered sense of taste
- diarrhea
- high blood pressure
- muscle aches

These are not all the possible side effects of PAXLOVID. Not many people have taken PAXLOVID. Serious and unexpected side effects may happen. PAXLOVID 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 PAXLOVID, FDA may allow for the emergency use of other medicines to treat people with COVID-19. Go to <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization> for information on the emergency use of other medicines that are authorized by FDA to treat people with COVID-19. Your healthcare provider may talk with you about clinical trials for which you may be eligible.

It is your choice to be treated or not to be treated with PAXLOVID. Should you decide not to receive it or for your child not to receive it, it will not change your standard medical care.

**What if I am pregnant or breastfeeding?**

There is no experience treating pregnant women or breastfeeding mothers with PAXLOVID. For a mother and unborn baby, the benefit of taking PAXLOVID may be greater than the risk from the treatment. If you are pregnant, discuss your options and specific situation with your healthcare provider.

It is recommended that you use effective barrier contraception or do not have sexual activity while taking PAXLOVID.

If you are breastfeeding, discuss your options and specific situation with your healthcare provider.

**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 or you can report side effects to Pfizer Inc. at the contact information provided below.

Website	Fax number	Telephone number
<a href="http://www.pfizersafetyreporting.com">www.pfizersafetyreporting.com</a>	1-866-635-8337	1-800-438-1985

**How should I store PAXLOVID?**

Store PAXLOVID tablets at room temperature, between 68°F to 77°F (20°C to 25°C).

**How can I learn more about COVID-19?**

- Ask your healthcare provider.
- Visit <https://www.cdc.gov/COVID19>.
- Contact your local or state public health department.

**What is an Emergency Use Authorization (EUA)?**

The United States FDA has made PAXLOVID available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by a Secretary of Health and Human Service (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

PAXLOVID for the treatment of mild-to-moderate COVID-19 in adults and children [12 years of age and older weighing at least 88 pounds (40 kg)] with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death, has not undergone the same type of review as an FDA-approved product. In issuing an EUA under the COVID-19 public health emergency, the FDA has determined, among other things, that based on the total amount of scientific evidence available including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that the product may be effective for diagnosing, 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 diagnose, treat, or prevent such disease or condition, outweigh the known and potential risks of such product; and that there are no adequate, approved, and available alternatives.

All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic. The EUA for PAXLOVID is in effect for the duration of the COVID-19 declaration justifying emergency use of this product, unless terminated or revoked (after which the products may no longer be used under the EUA).

**Additional Information**

For general questions, visit the website or call the telephone number provided below.

Website	Telephone number
<p data-bbox="305 359 683 390"><a href="http://www.COVID19oralRx.com">www.COVID19oralRx.com</a></p> 	<p data-bbox="1032 443 1305 531">1-877-219-7225 (1-877-C19-PACK)</p>

[www.pfizermedinfo.com](http://www.pfizermedinfo.com) or call 1-800-438-1985 for more information.



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**Fact Sheet for Patients And Caregivers**  
**Emergency Use Authorization (EUA) 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.
  - You and your healthcare provider may decide that you should take molnupiravir during pregnancy if there are no other COVID-19 treatment options authorized by the FDA that are accessible or clinically appropriate for you.
  - If you and your healthcare provider decide that you should take molnupiravir during pregnancy, you and your healthcare provider should discuss the known and potential benefits and the potential risks of taking molnupiravir during pregnancy.

**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.

**Pregnancy Surveillance Program:**

- There is a pregnancy surveillance program for individuals who take molnupiravir during pregnancy. The purpose of this program is to collect information about the health of you and your baby. 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.msd.com](https://www.msd.com/pregnancyreporting).

**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.

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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 with mild-to-moderate coronavirus disease 2019 (COVID-19) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 including hospitalization or death, and for whom other COVID-19 treatment options authorized by the FDA are not accessible or clinically appropriate.

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to make molnupiravir available during the COVID-19 pandemic (for more details about an EUA please see “**What is an Emergency Use Authorization?**” at the end of this document). Molnupiravir is not an FDA-approved medicine in the United States. 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 an investigational medicine used to treat mild-to-moderate COVID-19 in adults:

- with positive results of direct SARS-CoV-2 viral testing, and
- who are at high risk for progressing to severe COVID-19 including hospitalization or death, and for whom other COVID-19 treatment options authorized by the FDA are not accessible or clinically appropriate.

The FDA has authorized the emergency use of molnupiravir for the treatment of mild-to-moderate COVID-19 in adults under an EUA. For more information on EUA, see the “**What is an Emergency Use Authorization (EUA)?**” 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?**

#### **Possible side effects of molnupiravir are:**

- See, “**What is the most important information I should know about molnupiravir?**”
- 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, FDA may allow for the emergency use of other medicines to treat people with COVID-19. Go to <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization> for more information.

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.

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).

### **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](http://www.cdc.gov/COVID19)
- Contact your local or state public health department.
- Call Merck Sharp & Dohme at 1-800-672-6372 (toll free in the U.S.)
- Visit [www.molnupiravir.com](http://www.molnupiravir.com)

### **What Is an Emergency Use Authorization (EUA)?**

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Molnupiravir for the treatment of mild-to-moderate COVID-19 in adults with positive results of direct SARS-CoV-2 viral testing, who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate, has not undergone the same type of review as an FDA-approved product. In issuing an EUA under the COVID-19 public health emergency, the FDA has determined, among other things, that based on the total amount of scientific evidence available including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that the product may be effective for diagnosing, 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 diagnose, treat, or prevent such disease or condition, outweigh the known and potential risks of such product; and that there are no adequate, approved, and available alternatives.

All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic. The EUA for molnupiravir is in effect for the duration of the COVID-19 declaration justifying emergency use of molnupiravir, unless terminated or revoked (after which molnupiravir may no longer be used under the EUA).

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 **MERCK & CO., INC.**, Whitehouse Station, NJ 08889, USA

For patent information: [www.msd.com/research/patent](http://www.msd.com/research/patent)

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