Information about the Paxlovid COVID-19 Treatment

FDA Approval: May 25, 2023

This fact sheet contains information about the Paxlovid antiviral treatment and is intended to help you make an informed decision about receiving treatment that may help reduce your risk of severe COVID-19 symptoms.

How does Paxlovid work?

Paxlovid is considered an antiviral medication, which consists of two oral medications that are given together as pills.[1] Paxlovid is given immediately after a COVID-19 diagnosis.[1]

Who is Paxlovid for?

Paxlovid treats mild to moderate COVID-19 in adults and pediatric patients ages 12 and over and weighing at least 40 kilograms/88 pounds. Patients must also have a current diagnosis of mild to moderate COVID-19, and be considered high risk of severe COVID-19, including hospitalization and/or death (see Figure 1).[1,2] **A positive PCR test is no longer required to receive Paxlovid**. Paxlovid is available by prescription only and should be initiated as soon as possible after diagnosis of COVID-19 and within five days of symptom onset.[1]

Paxlovid is not authorized for the pre-exposure or post-exposure prevention of COVID-19 or for initiation of treatment in those requiring hospitalization due to severe or critical COVID-19. Paxlovid is not a substitute for vaccination.[3]

Paxlovid is not recommended in patients with severe kidney or liver impairment. In patients with moderate renal impairment, a reduced Paxlovid dose is needed. Patients with kidney or liver problems should discuss with their healthcare provider whether Paxlovid is right for them.[1]

Paxlovid may reduce the efficacy of combined hormonal contraceptives. Patients are advised to use an effective alternative contraceptive method or an additional barrier method of contraception while taking Paxlovid.[1]

Figure 1: You are considered high-risk of severe illness from COVID-19 if you meet at least one of the following criteria.[2]

- Are 65 years of age or older
- Have a body mass index (BMI) equal to or over 25
- Are pregnant
- Have cancer
- Have a chronic kidney disease
- Have a chronic liver disease
- Have diabetes
- Have an immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Have a heart condition
- Have hypertension
- Have sickle cell disease
- Have a chronic lung disease such as…
    - Chronic obstructive pulmonary disease
    - Moderate to severe asthma
    - Interstitial lung disease
    - Cystic fibrosis
    - Pulmonary hypertension
- Have a neurodevelopmental disorder such as cerebral palsy
- Have a mental health condition
- Have a medical-related technological dependence, such as a tracheostomy or gastrostomy

This list does not include all medical conditions that place a person at higher risk of severe illness from COVID-19. It is important that you talk with your healthcare provider about your risk.

Taking Paxlovid with certain medicines may cause serious or life-threatening side effects or affect how Paxlovid works (see Figure 2). Do not take Paxlovid if you are allergic to any of the ingredients in Paxlovid.[1]

How is Paxlovid given?

Paxlovid is administered as three tablets (two 150mg tablets of nirmatrelvir and one 100mg tablet of ritonavir) taken together orally twice daily for five days, for a total of 30 tablets. Paxlovid is not authorized for use for longer than five consecutive days.[3] Paxlovid is a prescription-only medication to be initiated as soon as possible after diagnosis and within three days of symptom onset.[1]

What are the benefits of receiving Paxlovid?

Benefits of treatment with Paxlovid include the following[1,4]:

- Reduced risk of severe COVID-19 symptoms
- Reduced risk of hospitalization
- Reduced risk of death from COVID-19
- Reduced risk of Post–COVID-19 conditions
- Oral treatment eliminates the time needed to receive the alternative infusion treatment in a medical setting, and treatment may be completed at home

What are the possible risks of receiving Paxlovid?

Possible side effects of Paxlovid include the following[5]:

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, or 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 the following[5]:

- Altered sense of taste
- Diarrhea
- High blood pressure

Paxlovid is still being studied, so it is possible that all risks are not known at this time.[5]

Is Paxlovid safe?

In preclinical studies, Paxlovid did not show evidence of human DNA mutations.[1] The FDA has determined that it is reasonable to believe that Paxlovid may be effective for treating mild to moderate COVID-19 in authorized patients. The agency has also determined that potential benefits of Paxlovid—when used consistent with the terms and conditions of the authorization—outweigh the potential risks of the product.[5] Paxlovid is the first authorized oral treatment for COVID-19.[3]

Where can I receive Paxlovid treatment for COVID-19?

Paxlovid may only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe anti-infective drugs.[1]

Resources

1. Fact sheet for healthcare providers: Emergency use authorization for Paxlovid. *FDA*. fda.gov/media/155050/download. Published December 22, 2021. Updated May 25, 2023. Accessed May 25, 2023.
2. People with certain medical conditions. *CDC*. Accessed April 14, 2022. cdc.gov/coronavirus/2019-ncov/need-extraprecautions/people-with-medical-conditions.html
3. Coronavirus (COVID-19) update: FDA authorizes additional oral antiviral for treatment of COVID-19 in certain adults. *FDA*. fda.gov/news-events/pressannouncements/coronavirus-covid-19-update-fda-authorizes-first-oralantiviral-treatment-covid-19. Published December 23, 2021. Accessed January 26, 2022.
4. Xie Y, Choi T, Al-Aly Z. Association of treatment with Nirmatrelvir and the risk of Post–COVID-19 condition. *JAMA Intern Med*. 2023;183(6):554–564. doi:10.1001/jamainternmed.2023.0743
5. Fact sheet for patients, parents, and caregivers: Emergency use authorization (EUA) of Paxlovid for Coronavirus Disease 2019 (COVID19). *FDA*. fda.gov/media/155051/download. Published December 22, 2021. Accessed January 25, 2022.