Product Focus

PAXLOVID

HEALTHDIRECT PHARMACY SERVICES

January 2022

PAXLOVID Oral Antiviral Treatment for COVID-19

The FDA has recently granted **emergency use authorization** (EUA) for **PAXLOVID**. **Paxlovid** is nirmatrelvir tablets co-packaged with ritonavir tablets, both antiviral agents. Both agents must be administered together. In clinical trials, PAXLOVID significantly reduced the risk of hospitalization or death for any cause by 89% compared to placebo in non-hospitalized, high-risk adult patients with COVID-19 treated within three days of symptom onset.

The EUA specifies that Paxlovid is for the treatment of mild-to-moderate coronavirus disease (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kilograms or about 88 pounds) ***with positive results of direct SARS-CoV-2 testing, and who are at high risk for progression to severe COVID-19***, including hospitalization or death. It is not authorized for initiation of treatment in patients requiring hospitalization due to severe COVID-19 or for pre-exposure or post-exposure prophylaxis for prevention of COVID-19.

Dosing: Adult

COVID-19, treatment, mild to moderate: Oral: Nirmatrelvir 300 mg (two 150 mg tablets) with ritonavir 100 mg (one 100 mg tablet), administered together, twice daily for 5 days; initiate as soon as possible after COVID-19 diagnosis, and within 5 days of symptom onset. **Prescriptions should specify the numeric dose of each active ingredient within PAXLOVID**. Patients who require hospitalization due to severe or critical COVID-19 after initiating treatment should complete the full 5-day treatment course per healthcare provider's discretion (FDA 2021). **Administer orally with or without food, the tablets should be swallowed whole and not chewed, broken, or crushed.**

Missed Dose:

If a dose is missed within 8 hours of usual administration time, the missed dose should be administered as soon as possible, and normal dosing schedule should resume. If a dose is missed by more than 8 hours, the missed dose should not be administered, and dosing should resume at the next scheduled administration time. Do not double the dose to make up for a missed dose (FDA 2021).

Dosing: Renal Impairment: Adult

eGFR ≥60 mL/minute: No dosage adjustment necessary (FDA 2021).

eGFR ≥30 to <60 mL/minute: 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. **Note**: Refer to Important Paxlovid EUA Dispensing Information for Patients with Moderate Renal Impairment for dispensing of nirmatrelvir and ritonavir in this population (FDA 2021).

eGFR <30 mL/minute: Use is not recommended at this time (FDA 2021).

Dosing: Hepatic Impairment: Adult

Severe impairment (Child-Pugh class C): Use is not recommended (has not been studied) (FDA 2021).

Dosage Adjustment for Concomitant Therapy:

Significant drug interactions exist, requiring dose/frequency adjustment or avoidance. Consult drug interactions database for more information.

***Note*:**

Distribution of this medication is being managed by state and federal agencies.

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Adverse Reactions:

Refer to EUA for information regarding reporting adverse reactions (FDA 2021). Adverse reactions reported in adults. 1% to 10%: Cardiovascular: Hypertension (1%), Gastrointestinal: Diarrhea (3%), dysgeusia (6%), Neuromuscular & skeletal: Myalgia (1%).

Drug Interactions:

PAXLOVID is ***contraindicated*** ***with drugs that are highly dependent on CYP3A for clearance*** and for which elevated concentrations are associated with serious and/or life-threatening reactions: *Alfuzosin, pethidine, piroxicam, propoxyphene, ranolazine, amiodarone, dronedarone, flecainide, propafenone, quinidine, colchicine, lurasidone, pimozide, clozapine, dihydroergotamine, ergotamine, methylergonovine, lovastatin, simvastatin, sildenafil, triazolam, oral midazolam*.

PAXLOVID is ***contraindicated*** ***with drugs that are potent CYP3A inducers*** (eg, apalutamide, carbamazepine, phenobarbital, phenytoin, rifampin, St. John's wort). **It CANNOT** be started immediately after discontinuation of any of these medications due to the delayed offset of the recently discontinued inducer.

PAXLOVID is ***contraindicated*** ***in patients with a history of clinically significant hypersensitivity reactions*** (eg, toxic epidermal necrolysis [TEN] or Stevens-Johnson syndrome) to its active ingredients (nirmatrelvir or ritonavir) or any other components of the product.

For complete prescribing information, please review the full emergency use authorization along with the information for healthcare providers when making treatment decisions.

See Emergency Use Authorization information for Healthcare Providers at: https://www.fda.gov/media/155050/download.

Storage/Stability:

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) (FDA 2021).

Reference:

UPTODATE