

INDICATIONS (must meet all criteria)

- Adults and children 12 and older (≥ 40 kg or 88lb)
- Have tested positive for SARS-CoV-2 (PCR or antigen)
- Are within 5 days of symptom onset
- High risk for progression to severe COVID-19 (see Appendix A)

PAXLOVID (nirmatrelvir/ ritonavir)

CONTRAINDICATIONS

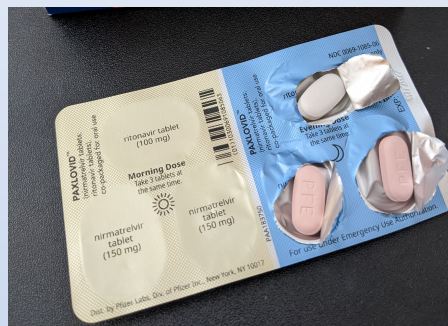
- Severe renal impairment (eGFR < 30 mL/min)
- Severe hepatic impairment (Child-Pugh Class C or higher)
- History of severe hypersensitivity reactions (TEN, SJS) to the drug's components
- Medication interaction (see Appendix B)

DOSAGE

Each carton contains 5 blister cards, each blister card contains 6 tablets:

- 4 nirmatrelvir (pink) tablets (150 mg each)
- 2 ritonavir (white) tablets (100 mg each)

Take 2 pink capsules (300 mg total nirmatrelvir) with 1 white capsule (100 mg ritonavir) twice daily for 5 days



wikipedia.org

For patients with renal impairment:

mild renal impairment.....no dose adjustment needed (eGFR ≥ 60 to < 90 mL/min)
moderate renal impairment.....150 mg nirmatrelvir and 100 mg ritonavir twice daily for 5 days (eGFR ≥ 30 to < 60 mL/min)
severe renal impairment.....not recommended until more data are available (eGFR < 30)

For patients with hepatic impairment

mild or moderate hepatic impairment.....no dose adjustment needed (Child-Pugh Class A or B)
Severe hepatic impairment.....not recommended until more data are available (Child-Pugh Class C or higher)

PATIENT EDUCATION

- Paxlovid is under Emergency Use Authorization by the FDA. Clinical data are limited.
 - In 2,246 unvaccinated patients with mild to moderate COVID-19, initiation of Paxlovid within 5 days of symptom onset reduced the risk of hospitalization or death through Day 28 by 89% compared to placebo
 - Adverse effects observed in the trial were loss of taste, diarrhea, hypertension, myalgia. Hypersensitivity reactions have been reported since the trial.
 - Ritonavir has been associated with hepatotoxicity and development of HIV-1 resistance in undiagnosed or untreated HIV-1-positive individuals
 - There is no human data on nirmatrelvir in pregnancy or breastfeeding
 - Ritonavir may reduce the efficacy of combined hormonal contraceptives. Patients should use an additional barrier method of contraception while taking Paxlovid.
- Patients should complete the full 5-day treatment (even if hospitalized during that time)
- If a dose is missed, take then missed dose within 8 hours. If more than 8 hours have passed, take the next dose at the regularly scheduled time

Appendix A: Medical conditions associated with higher risk for severe COVID-19

- ✓ Age ≥ 65 years old
- ✓ Cancer
- ✓ Chronic kidney disease
- ✓ Chronic lung disease (including mod to severe asthma)
- ✓ Cystic fibrosis
- ✓ Dementia
- ✓ Diabetes (type 1 or 2)
- ✓ Disabilities
- ✓ Heart Disease
- ✓ Hypertension
- ✓ Immunocompromised state
- ✓ Mental health conditions
- ✓ Overweight or obesity (BMI ≥ 25kg/m³)
- ✓ Physical inactivity
- ✓ Pregnancy
- ✓ Sickle cell disease/thalassemia
- ✓ Smoking (current or former)
- ✓ Solid organ or blood stem cell transplant
- ✓ Stroke or cerebrovascular disease
- ✓ Substance use disorders
- ✓ Tuberculosis
- ✓ HIV infection

Appendix B: Drug interactions for which Paxlovid is contraindicated

CYP4A substrates (Paxlovid leads to dangerously elevated concentrations of these drugs)

- Alpha1-adrenoreceptor antagonist: alfuzosin
- Analgesics: pethidine, propoxyphene
- Antianginal: ranolazine
- Antiarrhythmic: amiodarone, dronedarone, flecainide, propafenone, quinidine
- Anti-gout: colchicine
- Antipsychotics: lurasidone, pimozide, clozapine
- Ergot derivatives: dihydroergotamine, ergotamine, methylergonovine
- HMG-CoA reductase inhibitors: lovastatin, simvastatin
- PDE5 inhibitor: sildenafil (Revatio®) when used for pulmonary arterial hypertension (PAH)
- Sedative/hypnotics: triazolam, oral midazolam

CYP4A inducers (these drugs lead to reduced concentrations of Paxlovid and may contribute to loss of virologic response and potential resistance)

- Anticancer drugs: apalutamide
- Anticonvulsant: carbamazepine, phenobarbital, phenytoin
- Antimycobacterials: rifampin
- Herbal products: St. John's Wort

Many medications interact with Paxlovid, but are not absolute contraindications

For a full list of drug-drug interactions, refer to the EUA fact sheet:

<https://www.fda.gov/media/155050/download>

References

CDC "People with Certain Medical Conditions"

<https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>

FDA "Fact Sheet for Healthcare Provider: Emergency Use Authorization for Paxlovid"

<https://www.fda.gov/media/155050/download>

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