Nirmatrelvir tablets; Ritonavir tablets (PAXLOVID™)

Point of Care Resource

PAXLOVID is approved for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults who are at high risk for progression to severe COVID-19, including hospitalization or death.[1]

PAXLOVID has not been approved, but has been authorized for emergency use by FDA under an EUA, for the treatment of mild-to-moderate COVID-19 in pediatric patients (12 years of age and older weighing at least 40 kg) who are at high risk for progression to severe COVID-19, including hospitalization or death.[2]

The emergency use of PAXLOVID is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner.[2]

Limitations of Use

PAXLOVID is not approved for use as pre-exposure or post-exposure prophylaxis for prevention of COVID-19.[1]

WARNING: SIGNIFICANT DRUG INTERACTIONS WITH PAXLOVID[1]

See full prescribing information for complete boxed warning.

- **PAXLOVID includes ritonavir, a strong CYP3A inhibitor, which may lead to greater exposure of certain concomitant medications, resulting in potentially severe, life threatening, or fatal events.**
- **Prior to prescribing PAXLOVID:**
  1. **Review all medications taken by the patient to assess potential drug-drug interactions with a strong CYP3A inhibitor like PAXLOVID and**
  2. **Determine if concomitant medications require a dose adjustment, interruption, and/or additional monitoring**
- **Consider the benefit of PAXLOVID treatment in reducing hospitalization and death, and whether the risk of potential drug-drug interactions for an individual patient can be appropriately managed.**

This document consists of educational, background information only for healthcare providers prescribing PAXLOVID. This document does not represent all available resources prepared by Pfizer or third parties regarding COVID-19 treatments or PAXLOVID. This document does not contain medical advice and should not be used as a substitute for a practitioner's clinical judgment regarding treatment based on a patient's individualized medical history or symptoms. This resource and/or the underlying materials are subject to change.

Please see the Full Prescribing Information and Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers for PAXLOVID on important treatment considerations.

1. *PAXLOVID™ [prescribing information]. New York, NY: Pfizer Inc.; May 2023.*
2. *PAXLOVID™ (nirmatrelvir tablets; ritonavir tablets) Emergency Use Authorization Fact Sheet for Healthcare Providers. Pfizer Inc.*

Pfizer Medical Affairs

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1. Important Nirmatrelvir tablets; Ritonavir tablets (PAXLOVID) Information

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Who can be treated with Nirmatrelvir tablets; Ritonavir tablets (PAXLOVID)?

Legend: Meets Criteria | Does not meet Criteria

What is the **status** of the patient's COVID-19 illness?[1,2]

Asymptomatic/Presymptomatic | **Mild** | **Moderate** | Severe | Critical

For more information on the clinical spectrum of SARS-CoV-2 infection, please see NIH resource here.[3]

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What is the patient's **age?**

Adult ≥18 years — Approved for use per US Prescribing Information[1]

Pediatric ≥12 years & ≥40 kg — Authorized for use per Emergency Use Authorization (EUA)[2]

What is the patient's **risk** for progression to severe COVID-19?[1,2]

High Risk | Standard Risk

For more information on potential risk factors for severe illness or complications, see CDC guidance here.[4]

This link leads to a website that is owned and operated by CDC. Pfizer is not responsible for the content or maintenance of this site.

When did **symptoms begin**?[1,2]

Within the last 5 days | Prior to the last 5 days

The 5-day treatment course of PAXLOVID should be initiated as soon as possible after a diagnosis of COVID-19 has been made, and within 5 days of symptom onset even if baseline COVID-19 symptoms are mild.

Does the patient have any **contraindications**?[1,2]

No | Yes

Consult the PAXLOVID Prescribing Information and EUA Fact Sheet for Healthcare Providers for comprehensive information.

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2. *PAXLOVID™ (nirmatrelvir tablets; ritonavir tablets) Emergency Use Authorization Fact Sheet for Healthcare Providers. Pfizer Inc.*
3. *National Institutes of Health. Clinical Spectrum of SARS-CoV-2 Infection. Available at: https://www.covid19treatmentguidelines.nih.gov/overview/clinical-spectrum/. Accessed May 2024.*
4. *Centers for Disease Control and Prevention. Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Professionals. Available at: https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html. Accessed May 2024.*

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Dosage and Administration

PAXLOVID contains two different drugs (nirmatrelvir tablets and ritonavir tablets) that are co-packaged in a daily blister card for oral use. PAXLOVID is available in the following two packaging configurations:

300 mg; 100 mg Dose Pack

300 mg; 100 mg Dose Pack: This packaging configuration should be used for patients with normal renal function or mild renal impairment (eGFR* ≥60 to <90 mL/min).

The 300 mg; 100 mg Dose Pack is a carton containing 10 blister cards. Each blister card contains **300 mg nirmatrelvir** (two oval, pink, 150 mg immediate-release, film-coated tablets) and **100 mg ritonavir** (one white, film-coated, ovaloid tablet or one white to off-white, capsule-shaped, film-coated tablet).

How to take PAXLOVID 300 mg; 100 mg Dose Pack

Morning Dose

Take the 2 pink nirmatrelvir tablets and 1 white to off-white ritonavir tablet together at the same time each morning.

Evening Dose

Take the 2 pink nirmatrelvir tablets and 1 white to off-white ritonavir tablet together at the same time each evening.

150 mg; 100 mg Dose Pack

150 mg; 100mg Dose Pack: This packaging configuration should be used for patients with moderate renal impairment (eGFR* ≥30 to <60mL/min).

The 150 mg; 100 mg Dose Pack is a carton containing 10 blister cards. Each blister card contains **150 mg nirmatrelvir** (one oval, pink, immediate-release, film-coated tablet) and **100 mg ritonavir** (one white, film-coated ovaloid tablet).

How to take PAXLOVID 150 mg; 100 mg Dose Pack

Morning Dose

Take the 1 pink nirmatrelvir tablet and 1 white to off-white ritonavir tablet together at the same time each morning.

Evening Dose

Take the 1 pink nirmatrelvir tablet and 1 white to off-white ritonavir tablet together at the same time each evening.

- PAXLOVID is not recommended in patients with severe renal impairment (eGFR<30 mL/min) as the appropriate dose has not been determined.
- PAXLOVID is not recommended in patients with severe hepatic impairment (Child-Pugh Class C) as no pharmacokinetic or safety data are available in subjects with severe hepatic impairment.

*eGFR=estimated glomerular filtration rate based on the Chronic Kidney Disease-Epidemiology Collaboration (CKD-EPI) formula

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Contraindications

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

PAXLOVID is contraindicated with drugs that are primarily metabolized by CYP3A and for which elevated concentrations are associated with serious and/or life-threatening reactions and drugs that are strong CYP3A inducers where significantly reduced nirmatrelvir or ritonavir plasma concentrations may be associated with the potential for loss of virologic response and possible resistance. There are certain other drugs for which concomitant use with PAXLOVID should be avoided and/or dose adjustment, interruption, or therapeutic monitoring is recommended. Drugs listed in this section are a guide and not considered a comprehensive list of all drugs that may be contraindicated with PAXLOVID. The healthcare provider should consult other appropriate resources such as the prescribing information for the interacting drug for comprehensive information on dosing or monitoring with concomitant use of a strong CYP3A inhibitor like PAXLOVID.

PAXLOVID is contraindicated with drugs that are primarily metabolized by CYP3A for clearance and for which elevated concentrations are associated with serious and/or life-threatening reactions:

- Alpha1-adrenoreceptor antagonist: alfuzosin
- Antianginal: ranolazine
- Antiarrhythmic: amiodarone, dronedarone, flecainide, propafenone, quinidine
- Anti-gout: colchicine
- Antipsychotics: lurasidone, pimozide
- Benign prostatic hyperplasia agents: silodosin
- Cardiovascular agents: eplerenone, ivabradine
- Ergot derivatives: dihydroergotamine, ergotamine, methylergonovine
- HMG-CoA reductase inhibitors: lovastatin, simvastatin (these drugs can be temporarily discontinued to allow PAXLOVID use)
- Immunosuppressants: voclosporin
- Microsomal triglyceride transfer protein inhibitor: lomitapide
- Migraine medications: eletriptan, ubrogepant
- Mineralocorticoid receptor antagonists: finerenone
- Opioid antagonists: naloxegol
- PDE5 inhibitor: sildenafil (Revatio®) when used for pulmonary arterial hypertension (PAH)
- Sedative/hypnotics: triazolam, oral midazolam
- Serotonin receptor 1A agonist/serotonin receptor 2A antagonist: flibanserin
- Vasopressin receptor antagonists: tolvaptan

PAXLOVID is contraindicated with drugs that are strong CYP3A inducers where significantly reduced nirmatrelvir or ritonavir plasma concentrations may be associated with the potential for loss of virologic response and possible resistance. PAXLOVID cannot be started immediately after discontinuation of any of the following medications due to the delayed offset of the recently discontinued CYP3A inducer:

- Anticancer drugs: apalutamide
- Anticonvulsant: carbamazepine, phenobarbital, primidone, phenytoin
- Cystic fibrosis transmembrane conductance regulator potentiators: lumacaftor/ivacaftor
- Antimycobacterials: rifampin, rifapentine
- Herbal products: St. John's Wort *(hypericum perforatum)*

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Warnings and Precautions

Hypersensitivity reactions

Anaphylaxis, serious skin reactions (including Toxic Epidermal Necrolysis and Stevens-Johnson syndrome), and other hypersensitivity reactions have been reported with PAXLOVID. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue PAXLOVID and initiate appropriate medications and/or supportive care.

Hepatotoxicity

Hepatic transaminase elevations, clinical hepatitis, and jaundice have occurred in patients receiving ritonavir. Therefore, caution should be exercised when administering PAXLOVID to patients with pre-existing liver diseases, liver enzyme abnormalities, or hepatitis.

Risk of HIV-1 Resistance Development

Because nirmatrelvir is co-administered with ritonavir, there may be a risk of HIV-1 developing resistance to HIV protease inhibitors in individuals with uncontrolled or undiagnosed HIV-1 infection.

Adverse Reactions

Clinical Trials Experience

The safety of PAXLOVID is based on two Phase 2/3 randomized, placebo-controlled trials in symptomatic adult subjects ≥18 years of age with a laboratory confirmed diagnosis of SARS-CoV-2 infection.

Adverse reactions reported in the PAXLOVID group (≥1%) in the phase 3 EPIC-HR study that occurred at a greater frequency compared to placebo were dysgeusia (5% and <1%, respectively) and diarrhea (3% and 2%, respectively).

Adverse reactions reported in the phase 3 EPIC-SR study were consistent with those observed in EPIC-HR.

Adverse Reactions from Emergency Use Authorization Experience

Adverse reactions reported voluntarily during use of PAXLOVID under Emergency Use Authorization include:

- *Immune System Disorders:* Anaphylaxis, hypersensitivity reactions
- *Skin and Subcutaneous Tissue Disorders:* Toxic Epidermal Necrolysis, Stevens-Johnson syndrome
- *Nervous System Disorders:* Headache
- *Vascular Disorders:* Hypertension
- *Gastrointestinal Disorders:* Abdominal pain, nausea, vomiting
- *General Disorders and Administration Site Conditions:* Malaise

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Important Information Related to Drug Interactions

In the Full Prescribing Information, you'll find a table for clinically significant drug interactions, including contraindicated drugs. This table contains drug classes in alphabetical order, drugs within each class, the effect on concentration of concomitant medications or PAXLOVID, and clinical comments. The clinical comments provide potential adverse events that may result in an interaction and provide recommendations, where applicable, to manage these drug interactions. Drugs listed in the table are a guide and not considered a comprehensive list of all possible drugs that may interact with PAXLOVID. The healthcare provider should consult appropriate references for comprehensive information.

Resources to Help Identify and Manage Drug-Drug Interactions with PAXLOVID (nirmatrelvir tablets; ritonavir tablets)

Pfizer Medical Resources

- Full Prescribing Information
- PAXLOVID Medical Information Page, which includes a drug interaction tool
- Potentially Significant Drug Interactions, Including Contraindicated Drugs Resource

Third-party Resources

- NIH Guideline on Drug-Drug Interactions Between Ritonavir-Boosted Nirmatrelvir (PAXLOVID) and Concomitant Medications
- The University of Liverpool COVID-19 Drug Interactions website

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Use in Patients with Renal Impairment or Hepatic Impairment

Renal Impairment

Renal impairment increases nirmatrelvir exposure, which may increase the risk of PAXLOVID adverse reactions. No dosage adjustment is recommended in patients with mild renal impairment (eGFR ≥60 to <90 mL/min). Reduce the PAXLOVID dosage in patients with moderate renal impairment (eGFR ≥30 to <60 mL/min).

PAXLOVID is not recommended for use in patients with severe renal impairment (eGFR <30 mL/min) or patients with end stage renal disease (eGFR <15 mL/min) receiving dialysis until more data are available. The appropriate dosage for patients with severe renal impairment has not been determined.

Hepatic Impairment

No dosage adjustment of PAXLOVID is recommended for patients with either mild (Child-Pugh Class A) or moderate (Child-Pugh Class B) hepatic impairment. No pharmacokinetic or safety data are available regarding the use of nirmatrelvir or ritonavir in subjects with severe hepatic impairment (Child-Pugh Class C), therefore, PAXLOVID is not recommended for use in patients with severe hepatic impairment.

Use During Pregnancy/Lactation

Available data on the use of nirmatrelvir during pregnancy are insufficient to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes or for PAXLOVID-associated risk to breastfeeding mothers and infants.

Untreated COVID-19 during pregnancy is associated with adverse maternal and fetal outcomes.

Currently, there are no data on the presence of nirmatrelvir in human or animal milk, the effects on the breastfed infant, or the effects on milk production.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for PAXLOVID and any potential adverse effects on the infant from PAXLOVID.

Breastfeeding individuals with COVID-19 should follow practices according to clinical guidelines to avoid exposing the infant to COVID-19.

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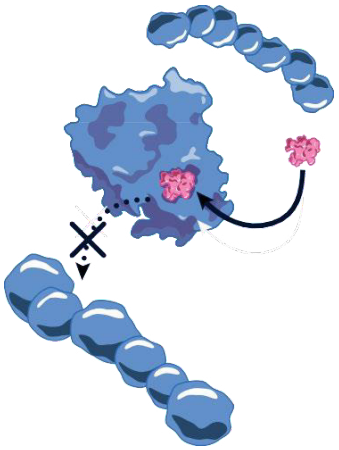
Mechanism of Action



Nirmatrelvir is a peptidomimetic inhibitor of the SARS-CoV-2 main protease (M^{pro}). Inhibition of SARS-CoV-2 M^{pro} renders it incapable of processing polyprotein precursors, preventing viral replication.

Ritonavir is an HIV-1 protease inhibitor, but is not active against SARS-CoV-2 M^{pro}. Ritonavir inhibits the CYP3A-mediated metabolism of nirmatrelvir, resulting in increased plasma concentrations of nirmatrelvir.

A PAXLOVID Mechanism of Action video and interactive infographic can be found at Pfizer Medical Portal.

Clinical Studies

- The data supporting PAXLOVID is based on the analysis of Evaluation of Protease Inhibition for COVID-19 in High-Risk Patients [EPIC-HR] (NCT04960202), a Phase 2/3, randomized, double-blind, placebo-controlled study in non-hospitalized symptomatic adult subjects with a laboratory confirmed diagnosis of SARS-CoV-2 infection.

- For more information on the efficacy and safety data of PAXLOVID in the EPIC-HR Trial, please visit the Full Prescribing Information for Healthcare Providers, section 14 (Clinical Studies) and section 6 (Adverse Reactions).

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Patient Counseling

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Patients should be informed that PAXLOVID may interact with certain drugs and is contraindicated for use with certain drugs; therefore, advise patients to report to their healthcare provider the use of any prescription, non-prescription medication, or herbal products.

Patients should be informed that hypersensitivity reactions have been reported with PAXLOVID and advised to discontinue the drug and inform their healthcare provider at the first sign of an allergic reaction.

Patients with moderate renal impairment should take one 150 mg nirmatrelvir tablet with one 100 mg ritonavir tablet together twice daily for 5 days.

Patients should take PAXLOVID with or without food as instructed.

Patients should swallow all tablets for PAXLOVID whole and not chew, break, or crush the tablets.

Patients should complete the full 5-day treatment course and continue isolation in accordance with public health recommendations.

If the patient misses a dose of PAXLOVID **within 8 hours** of the time it is usually taken, the patient should **take it as soon as possible and resume the normal dosing schedule**

If the patient misses a dose by **more than 8 hours,** the patient **should not take the missed dose** and instead take the **next dose at the regularly scheduled time**

The patient should not double the dose to make up for a missed dose

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2. High Risk Factors Associated with Progression to Severe COVID-19

- Full Prescribing Information
- Fact Sheet for Healthcare Providers
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- FDA Emergency Use Authorization Letter

Severe outcomes of COVID-19 are defined as...

- Hospitalization
- Admission to the intensive care unit (ICU)
- Intubation or mechanical ventilation
- Death

Providers should consider the patient's age, underlying medical conditions, vaccination status, and other risk factors in determining the risk of severe COVID-19 outcomes for any patient

Age ≥50 years

The strongest risk factor for severe COVID-19 outcomes is age

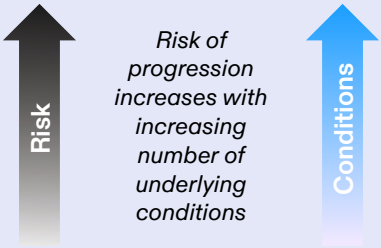
*Risk of COVID-19-related death among people ages **50–64 years** is*

25x ***higher*** *than those ages **18–29 years***

Risk is even higher at ages > 65 years

Underlying Conditions

Patients with **certain underlying medical conditions are at high risk for severe COVID-19**



Risk of progression increases with increasing number of underlying conditions

COVID-19 Vaccination Status

Being unvaccinated or not being up to date on COVID-19 vaccinations increases the risk of severe disease

Race and Ethnicity

Race and ethnicity are risk markers for other underlying conditions that affect health, including socioeconomic status, access to health care, and exposure to the virus related to occupation (e.g., front-line, essential, and critical infrastructure workers)

1. *Centers for Disease Control and Prevention. Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Professionals. Available at: https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html. Accessed May 2024.*

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2. High Risk Factors Associated with Progression to Severe COVID-19 Contd.

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 Age ≥50 years

 Underlying Medical Conditions

 COVID-19 Vaccination Status

 Race & Ethnicity

Higher Risk | *Meta Analysis or Systematic Review Demonstrated Good or Strong Evidence*

- Asthma
- Cancer, including hematologic malignancies
- Cerebrovascular disease
- Chronic kidney disease*, including dialysis
- Chronic lung diseases limited to:
  - Bronchiectasis, chronic obstructive pulmonary disease (COPD), interstitial lung disease, pulmonary embolism, pulmonary hypertension
- Chronic liver diseases limited to:
  - Cirrhosis, non alcoholic fatty liver disease, alcoholic liver disease, autoimmune hepatitis
- Cystic fibrosis
- Diabetes mellitus, type 1 and type 2*
- Disabilities‡:
  - Down syndrome
- Heart conditions (such as heart failure, coronary artery disease, or cardiomyopathies)
- HIV (human immunodeficiency virus)
- Mental health disorders limited to:
  - Mood disorders (including depression) and schizophrenia spectrum disorders
- Neurologic conditions limited to dementia‡
- Obesity (BMI ≥30 kg/m^2 or ≥95th percentile in children)
- Physical inactivity
- Pregnancy and recent pregnancy
- Primary immunodeficiencies
- Smoking, current and former
- Solid organ or blood stem cell transplantation
- Tuberculosis
- Use of corticosteroids or other immunosuppressive medications

Suggestive Higher Risk | *Evidence supported by mostly cohort, case-control, or cross-sectional studies (systematic reviews are available for some conditions in children with underlying conditions)*

- Children with certain underlying conditions
- Overweight (BMI ≥ 25 kg/m^2, but < 30 kg/m^2)
- Sickle cell disease
- Substance use disorders

Mixed Evidence | *Meta-analysis or systematic review is inconclusive*

- Alpha 1 antitrypsin deficiency
- Bronchopulmonary dysplasia
- Hepatitis B
- Hepatitis C
- Hypertension*
- Thalassemia

BMI, body mass index.

*indicates underlying conditions for which there is evidence for pregnant and non-pregnant people

‡underlying conditions for which there is evidence in pediatric patients

For a full and comprehensive list, visit: https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html

1. *Centers for Disease Control and Prevention. Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Professionals. Available at: https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html. Accessed May 2024.*

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3. Additional Medical Educational Resources

- Full Prescribing Information
- Fact Sheet for Healthcare Providers
- Fact Sheet for Patients, Parents, and Caregivers
- FDA Emergency Use Authorization Letter

Pfizer Medical Portal

- Who Can Be Treated With PAXLOVID?
- Identifying patients who are at high risk for progression to severe COVID-19, including hospitalization or death
- PAXLOVID Potentially Significant Drug Interactions
- Important PAXLOVID Dosage Information for Patients with Renal Impairment
- PAXLOVID Mechanism of Action

Resources Published by Third Parties

- FDA PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers
- NIH Guidelines For Ritonavir-Boosted Nirmatrelvir (PAXLOVID)

FDA, The Food and Drug Administration; NIH, National Institutes of Health.

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