Nirmatrelvir

Drug Information:  ○ AHFS Drug Information (comprehensive) ○ AHFS DI Essentials (point-of-care)

AHFS Class: 8:18.92 (tofc-08) — Antivirals, Miscellaneous

Nirmatrelvir and Ritonavir (Systemic) (AHFS Essentials)

Nirmatrelvir

Chemical Name: (1R,2S,5S)-N-((1S)-1-Cyano-2-((3S)-2-oxopyrrolidin-3-yl)ethyl)-3-((2S)-3,3-dimethyl-2-(2,2,2-trifluoroacetamido)butanoyl)-6,6-dimethyl-3-azabicyclo[3.1.0]hexane-2-carboxamide

Molecular Formula: C_{23}H_{32}F_{3}N_{5}O_{4}

Investigational Number: PF-07321332

Ritonavir

CAS Number: 155213-67-5

Chemical Name: [5S-(5R*,8R*,10R*,11R*)]10-(Hydroxy-2-methyl-5-(1-methylethyl)-1-[2-(1-methylethyl)-4-thiazolyl]-3,6-dioxo-8,11-bis(phenylmethyl)-2,4,7,12-tetraazatridecan-13-oic acid,5-thiazolylmethyl ester

Molecular Formula: C_{37}H_{48}N_{6}O_{5}S_{2}

Investigational Number: ABT-538

Synonym: RTV
Alert:
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Brands: Paxlovid™

Introduction

Antiviral; SARS-CoV-2 main protease (Mpro) inhibitor.¹

Uses

Coronavirus Disease 2019 (COVID-19)

Nirmatrelvir with low-dose ritonavir (ritonavir-boosted nirmatrelvir) is available under an emergency use authorization (EUA) for the treatment of mild to moderate COVID-19 in adults and pediatric patients (≥12 years of age weighing ≥40 kg) with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing who are at high risk of progression to severe COVID-19, including hospitalization or death.¹

Consult nirmatrelvir EUA letter of authorization ([Web](https://www.fda.gov/media/155049/download)),⁴ EUA fact sheet for healthcare providers ([Web](https://www.fda.gov/media/155050/download)),¹ and EUA fact sheet for patients, parents, and caregivers ([Web](https://www.fda.gov/media/155051/download))² for additional information.
Ritonavir-boosted nirmatrelvir is not authorized under the EUA for initiation of treatment in patients requiring hospitalization due to severe or critical COVID-19, those requiring hospitalization due to severe or critical COVID-19, or for use >5 consecutive days.¹

In nonhospitalized patients who require treatment for mild to moderate COVID-19, the NIH COVID-19 Treatment Guidelines Panel states that when logistical or supply constraints limit availability of SARS-CoV-2-specific monoclonal antibodies or oral antiviral agents because of high prevalence of the B.1.1.529 (Omicron) variant of concern (VOC), these drugs should be prioritized for patients who are at the highest risk of progressing to severe COVID-19.⁷ The Panel favors the use of ritonavir-boosted nirmatrelvir in most high-risk, nonhospitalized patients with mild to moderate COVID-19.⁷ If ritonavir-boosted nirmatrelvir is unavailable or cannot be used because of drug interactions, the Panel recommends using sotrovimab in patients who live in areas with a high prevalence of the Omicron VOC.⁷ If sotrovimab is unavailable, the Panel recommends using a 3-day course of remdesivir.⁷ Molnupiravir should only be administered when ritonavir-boosted nirmatrelvir, sotrovimab, and remdesivir are either not available or cannot be used.⁷

For the treatment of outpatients (ambulatory patients) with mild to moderate COVID-19 at high risk of progression to severe COVID-19, IDSA suggests the use of ritonavir-boosted nirmatrelvir within 5 days of symptom onset over no antiviral treatment.⁶ These experts state that patient-specific factors (e.g., symptom duration, renal function, concomitant drugs) as well as product availability should be considered when selecting an appropriate treatment for COVID-19 in outpatients.⁶ Based on clinical trial data to date, use of ritonavir-boosted nirmatrelvir early in the disease process when viral loads are high confers maximum benefit; therefore, it is critical to make a rapid diagnosis and treat outpatients with COVID-19 early in the disease course.⁶

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**Dosage and Administration**

- **General**
  
  **Pretreatment Screening**
  
  Baseline renal and liver function.¹

  **Dispensing and Administration Precautions**
  
  Prescriptions must specify numeric EUA-approved dosage of nirmatrelvir and ritonavir (e.g., 300 mg nirmatrelvir with 100 mg ritonavir).¹
  
  In patients with moderate renal impairment, daily blister cards contain more nirmatrelvir tablets than necessary.⁵ Consult manufacturer instructions for dispensing Paxlovid™ in patients with moderate renal impairment to remove extra doses of nirmatrelvir from each daily blister card.⁵
  
  Use ritonavir with caution in patients with preexisting liver disease, liver enzyme abnormalities, or hepatitis.¹

  **Completion of FDA MedWatch forms to report all medication errors and all serious adverse events potentially related to ritonavir-boosted nirmatrelvir is mandatory.**¹ ⁴  Consult FDA fact
Other General Considerations

Patients should continue isolation in accordance with public health recommendations to maximize viral clearance and minimize transmission of SARS-CoV-2.\(^1\)

Patients on ritonavir- or cobicistat-containing HIV or HCV treatment regimens should continue their treatment as indicated.\(^1\) No dosage adjustment is required when ritonavir-boosted nirmatrelvir is coadministered with other products containing ritonavir or cobicistat.\(^1\)

■ Administration

Oral Administration

Administer orally without regard to food.\(^1\)

Swallow tablets whole; do not chew, break, or crush.\(^1\)

**Must** administer nirmatrelvir in conjunction with low-dose ritonavir at the same time twice daily.\(^1\)

Ritonavir is a pharmacokinetic enhancer that improves the pharmacokinetic profile of nirmatrelvir.\(^1\)

Paxlovid™ is available as a 5-day blister pack; each daily blister card contains a morning dose (two 150-mg nirmatrelvir tablets and one 100-mg ritonavir tablet) and evening dose (two 150-mg nirmatrelvir tablets and one 100-mg ritonavir tablet).\(^1\)

If a dose of ritonavir-boosted nirmatrelvir is missed by ≤8 hours, take the prescribed dose as soon as possible.\(^1\) If a dose is missed by >8 hours, administer prescribed dose at the next scheduled time; do not administer an additional dose to replace the missed dose.\(^1\)

■ Dosage

**Pediatric Patients**

Outpatient Treatment of Mild to Moderate COVID-19.

**Oral**—≥12 years of age weighing ≥40 kg: FDA EUA permits use of 300 mg of nirmatrelvir (two 150 mg tablets) orally twice daily in conjunction with 100 mg of ritonavir (one 100 mg tablet) orally twice daily for 5 days (ritonavir-boosted nirmatrelvir) for the treatment of mild to moderate COVID-19.\(^1\) Complete full 5-day treatment course.\(^1\)

Administer ritonavir-boosted nirmatrelvir as soon as possible after positive viral test for SARS-CoV-2 and within 5 days of symptom onset.\(^1\)

If hospitalization occurs due to progression to severe or critical COVID-19 after initiation of ritonavir-boosted nirmatrelvir therapy, treatment course may be continued per the clinician’s discretion.\(^1\)

**Adults**
**Outpatient Treatment of Mild to Moderate COVID-19.**

**Oral**— EUA permits use of 300 mg of nirmatrelvir (two 150 mg tablets) orally twice daily in conjunction with 100 mg of ritonavir (one 100 mg tablet) orally twice daily for 5 days (*ritonavir-boosted* nirmatrelvir) for the treatment of mild to moderate COVID-19.¹ Complete full 5-day treatment course.¹

Administer *ritonavir-boosted* nirmatrelvir as soon as possible after positive viral test for SARS-CoV-2 and within 5 days of symptom onset.¹

If hospitalization occurs due to progression to severe or critical COVID-19 after initiation of *ritonavir-boosted* nirmatrelvir therapy, treatment course may be continued per the clinician’s discretion.¹

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**Special Populations**

**Dosage in Hepatic Impairment**

Mild or moderate hepatic impairment (Child-Pugh class A or B): No dosage adjustment of *ritonavir-boosted* nirmatrelvir necessary.¹

Severe hepatic impairment (Child-Pugh class C): Pharmacokinetic profile and safety of *ritonavir-boosted* nirmatrelvir not established; *ritonavir-boosted* nirmatrelvir not recommended in such patients.¹

**Dosage in Renal Impairment**

Moderate renal impairment (eGFR 30 to <60 mL/minute): Reduce nirmatrelvir dosage to 150 mg twice daily in conjunction with ritonavir 100 mg twice daily for 5 days.¹ Each daily blister card contains more nirmatrelvir tablets than needed for dosing in patients with moderate renal impairment.⁵ Prescribing clinicians must specify the numeric dose of nirmatrelvir and ritonavir (150 mg nirmatrelvir with 100 mg ritonavir for patients with moderate renal impairment) on prescriptions.⁵ Clinicians should consult manufacturer instructions for dispensing Paxlovid™ in patients with moderate renal impairment.⁵

Mild renal impairment (eGFR 60 to <90 mL/minute): No dosage adjustment of *ritonavir-boosted* nirmatrelvir necessary.¹

Severe renal impairment (eGFR <30 mL/minute): Appropriate dosage of *ritonavir-boosted* nirmatrelvir not established; not recommended in such patients.¹

**Geriatric Patients**

No specific dosage recommendations.¹

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**Cautions**

**Contraindications**
Must not be used in patients with a history of clinically significant hypersensitivity reactions (e.g., toxic epidermal necrolysis [TEN] or Stevens-Johnson syndrome) to any ingredient in the preparation.¹

Concomitant use of *ritonavir-boosted* nirmatrelvir with drugs highly dependent on CYP3A for metabolism and for which elevated plasma concentrations are associated with serious and/or life-threatening events (e.g., alfuzosin, meperidine, piroxicam, ranolazine, amiodarone, dronedarone, flecainide, propafenone, quinidine, colchicine, lurasidone, pimozone, clozapine, dihydroergotamine, ergotamine, methylergonovine, lovastatin, simvastatin, sildenafil [Revatio®] for treatment of pulmonary arterial hypertension, triazolam, oral midazolam) is contraindicated.¹

Concomitant use of *ritonavir-boosted* nirmatrelvir with potent CYP3A inducers for which reduced nirmatrelvir or ritonavir plasma concentrations may be associated with possible loss of virologic response (e.g., apalutamide, carbamazepine, phenobarbital, phenytoin, rifampin, St. John's wort [Hypericum perforatum]) is contraindicated.¹

**Warnings/Precautions**

*Interactions*

Must be used in conjunction with ritonavir.¹ Failure to administer nirmatrelvir with the recommended dosage of ritonavir will result in subtherapeutic nirmatrelvir concentrations and inadequate virologic response.¹ When *ritonavir-boosted* nirmatrelvir is used, the cautions, precautions, contraindications, and drug interactions associated nirmatrelvir and ritonavir should be considered.¹

Concomitant use of *ritonavir-boosted* nirmatrelvir with certain drugs is contraindicated or requires particular caution.¹ Concomitant use with some drugs may result in clinically important adverse effects, including severe, life-threatening, or fatal events, due to higher exposures of the concomitant drug or higher exposures of nirmatrelvir and/or ritonavir.¹ Concomitant use with other drugs may result in drug interactions leading to loss of therapeutic effect of *ritonavir-boosted* nirmatrelvir and possible development of viral resistance.¹ Because nirmatrelvir and ritonavir are inhibitors of CYP3A, concomitant use with drugs metabolized by CYP3A may increase plasma concentrations of CYP3A substrate drugs.¹

**Hepatotoxicity**

Hepatotoxicity (i.e., elevations in serum aminotransferase concentrations, clinical hepatitis, jaundice) reported in patients receiving ritonavir.¹

Ritonavir should be used with caution in patients with preexisting liver disease, liver enzyme abnormalities, or hepatitis.¹

**HIV Resistance**

Because nirmatrelvir is coadministered with ritonavir, cross-resistance to HIV protease inhibitors (HIV PIs) may occur in individuals with uncontrolled or undiagnosed HIV-1 infection.¹

**EUA Requirements for Patient Monitoring and Mandatory FDA MedWatch Reporting**
Safety and efficacy of ritonavir-boosted nirmatrelvir not established.\(^1\) FDA EUA that permits use of ritonavir-boosted nirmatrelvir for the treatment of mild to moderate COVID-19 in certain adults and pediatric patients requires use of dosages recommended in the EUA.\(^1\)

Only limited data available to date regarding adverse effects associated with ritonavir-boosted nirmatrelvir.\(^1\) Serious and unexpected adverse events may occur that have not been previously reported with use of the drugs together.\(^1\)

Completion of FDA MedWatch forms to report all medication errors and all serious adverse events potentially related to ritonavir-boosted nirmatrelvir is mandatory.\(^1,4\) Consult the FDA fact sheet for health care providers for requirements and instructions regarding reporting of adverse reactions and medication errors.\(^1\)

**Specific Populations**

**Pregnancy.**

*Nirmatrelvir*: Data are insufficient to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes.\(^1\) Reduced fetal body weight observed in animal studies.\(^1\)

*Ritonavir*: Published observational studies have not identified an increase in the risk of major birth defects when ritonavir was used in pregnant women.\(^1\) Published studies with ritonavir are insufficient to identify a drug-associated risk of miscarriage.\(^1\)

Estimated background risk of major birth defects and miscarriage in the indicated population unknown.\(^1\) COVID-19 in pregnancy is associated with adverse maternal and fetal outcomes, including preeclampsia, eclampsia, preterm birth, premature rupture of membranes, venous thromboembolic disease, and fetal death.\(^1\)

*For more information, see DART (https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+dart:%22Nirmatrelvir%22) (Developmental and Reproductive Toxicology Database).*

**Lactation.**

*Nirmatrelvir*: Not known whether nirmatrelvir is distributed into human or animal milk or has effects on the breast-fed infant or milk production.\(^1\)

*Ritonavir*: Limited published data indicate that ritonavir is present in human milk.\(^1\) Not known whether ritonavir has effects on the breast-fed infant or milk production.\(^1\)

Consider developmental and health benefits of breast-feeding along with the mother’s clinical need for ritonavir-boosted nirmatrelvir and any potential adverse effects on the breast-fed child from the drug or from the underlying maternal condition.\(^1\)

Females with COVID-19 who are breast-feeding should follow clinical guidelines to avoid exposing the infant to the virus.\(^1\)

**Pediatric Use.**
The FDA EUA permits use of **ritonavir-boosted nirmatrelvir** for the treatment of COVID-19 in certain pediatric patients ≥12 years of age weighing ≥40 kg. Use of **ritonavir-boosted nirmatrelvir** is not authorized for pediatric patients <12 years of age or those weighing <40 kg.

Safety and efficacy of **ritonavir-boosted nirmatrelvir** not established in pediatric patients.

Pharmacokinetics of **ritonavir-boosted nirmatrelvir** not evaluated in pediatric patients <18 years of age. EUA-recommended dosage of **ritonavir-boosted nirmatrelvir** is expected to result in plasma concentrations of the drugs in patients ≥12 years of age weighing ≥40 kg that are comparable to those observed in adults.

**Geriatric Use.**

In the EPIC-HR clinical trial, 13% of individuals who received **ritonavir-boosted nirmatrelvir** were ≥65 years of age and 3% were ≥75 years of age.

**Hepatic Impairment.**

Moderate hepatic impairment: Systemic exposure to nirmatrelvir not substantially altered following administration of **ritonavir-boosted nirmatrelvir**.

Severe hepatic impairment: **Ritonavir-boosted nirmatrelvir** not studied.

**Renal Impairment.**

Mild renal impairment (eGFR 60 to <90 mL/minute): Peak plasma concentrations or systemic exposure of nirmatrelvir increase by 30 or 24%, respectively, following administration of **ritonavir-boosted nirmatrelvir**.

Moderate renal impairment (eGFR 30 to <60 mL/minute): Peak plasma concentrations or systemic exposure of nirmatrelvir increase by 38 or 87%, respectively, following administration of **ritonavir-boosted nirmatrelvir**.

Severe renal impairment (eGFR <30 mL/minute): Peak plasma concentrations or systemic exposure of nirmatrelvir increase by 48 or 204%, respectively, following administration of **ritonavir-boosted nirmatrelvir**.

**Common Adverse Effects**

Most common adverse events occurring in ≥1% of patients receiving **ritonavir-boosted nirmatrelvir** and more frequently than placebo (≥5 subject difference) include dysgeusia (6 versus <1%), diarrhea (3 versus 2%), hypertension (1 versus <1%), and myalgia (1 versus <1%).

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**Interactions**

Nirmatrelvir must be used with a pharmacokinetic enhancer (i.e., low-dose ritonavir); consider drug interactions associated with both nirmatrelvir and ritonavir.
Nirmatrelvir: In vitro, nirmatrelvir is a substrate of P-glycoprotein (P-gp) and CYP3A4, but not a substrate of BCRP, MATE1, MATE2K, NTCP, OAT1, OAT2, OAT3, OCT1, OCT2, PEPT1, or OATPs 1B1, 1B3, 2B1, and 4C1.\(^1\) Does not reversibly inhibit CYP1A2, CYP2B6, CYP2C8, CYP2C9, CYP2C19, or CYP2D6 at clinically relevant concentrations.\(^1\) Nirmatrelvir has potential to reversibly and time-dependently inhibit CYP3A4 and P-gp.\(^1\) Does not induce CYP isoenzymes at clinically relevant concentrations.\(^1\)

Ritonavir: In vitro, ritonavir is primarily a substrate of CYP3A, and appears to be a substrate of CYP2D6.\(^1\) Ritonavir is an inhibitor of CYP3A and to a lesser extent CYP2D6.\(^1\) Appears to induce CYP3A, CYP1A2, CYP2C9, CYP2C19, and CYP2B6 as well as other enzymes, including glucuronosyl transferase.\(^1\)

The following drug interactions are based on studies using *ritonavir-boosted* nirmatrelvir.\(^1\)

### Drugs Affecting or Metabolized by Hepatic Microsomal Enzymes

**CYP3A Inducers**: Potential pharmacokinetic interaction with drugs that induce CYP3A (decreased plasma concentrations of nirmatrelvir and ritonavir which may lead to reduced virologic response).\(^1\)

### Substrates of CYP3A

**Substrates of CYP3A**: Potential pharmacokinetic interaction with drugs principally metabolized by CYP3A (increased plasma concentrations of drug metabolized by CYP3A).\(^1\) Concomitant use of nirmatrelvir and ritonavir with drugs highly dependent on CYP3A for metabolism and for which elevated plasma concentrations are associated with serious and/or life-threatening events is contraindicated.\(^1\) Concomitant use of nirmatrelvir and ritonavir with other CYP3A substrates may require dosage adjustment or additional monitoring.\(^1\)

### Specific Drugs

<table>
<thead>
<tr>
<th>Drug</th>
<th>Interaction</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alfuzosin</td>
<td>Possible increased alfuzosin concentrations and increased risk of serious and/or life-threatening reactions (e.g., hypotension)(^1).</td>
<td>Concomitant use contraindicated(^1).</td>
</tr>
<tr>
<td>Antiarrhythmic agents</td>
<td>Possible increased antiarrhythmic agent concentrations(^1).</td>
<td>Amiodarone, dronedarone, flecainide, propafenone, quinidine: Concomitant use contraindicated(^1).</td>
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<tr>
<td>(amiodarone, bepridil, dronedarone, flecainide, systemic lidocaine, propafenone, quinidine)</td>
<td></td>
<td>Bepridil, systemic lidocaine: Use with caution; monitor therapeutic concentrations, if available(^1).</td>
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<tr>
<td>Drug</td>
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<td>Comments</td>
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</tbody>
</table>
| Anticoagulants, oral (rivaroxaban, warfarin) | Rivaroxaban: Possible increased rivaroxaban concentrations and increased risk of bleeding<sup>1</sup>  
Warfarin: Possible altered warfarin concentrations<sup>1</sup> | Rivaroxaban: Avoid concomitant use<sup>1</sup>.  
Warfarin: Closely monitor INR if concomitant use with ritonavir-boosted nirmatrelvir is necessary<sup>1</sup>. |
| Anticonvulsants (carbamazepine, phenobarbital, phenytoin) | Carbamazepine: Possible decreased systemic exposure to nirmatrelvir and ritonavir, loss of virologic response, and development of nirmatrelvir resistance; possible increased carbamazepine concentrations<sup>1</sup>.  
Phenobarbital, phenytoin: Decreased systemic exposure to nirmatrelvir and ritonavir, loss of virologic response, and development of nirmatrelvir resistance; possible decreased phenobarbital or phenytoin concentrations<sup>1</sup>. | Concomitant use contraindicated; do not initiate ritonavir-boosted nirmatrelvir immediately after discontinuation of carbamazepine, phenobarbital, or phenytoin due to delayed offset of these drugs<sup>1</sup>. |
| Antifungals, azoles (isavuconazonium, itraconazole, ketoconazole, voriconazole) | Isavuconazonium (prodrug of isavuconazole): Possible increased isavuconazole concentrations and increased nirmatrelvir and ritonavir concentrations<sup>1</sup>.  
Itraconazole: Possible increased itraconazole concentrations and increased nirmatrelvir and ritonavir concentrations<sup>1</sup>.  
Ketoconazole: Possible increased ketoconazole concentrations and increased nirmatrelvir and ritonavir concentrations<sup>1</sup>.  
Voriconazole: Possible decreased voriconazole concentrations and increased nirmatrelvir and ritonavir concentrations<sup>1</sup>. | Voriconazole: Avoid concomitant use<sup>1</sup>. |
| Antimycobacterials (bedaquiline, rifabutin, rifampin) | Bedaquiline: Possible increased bedaquiline concentrations<sup>1</sup>.  
Rifabutin: Increased rifabutin concentrations<sup>1</sup>.  
Rifampin: Substantially decreased nirmatrelvir concentrations and possible loss of virologic response and development of resistance<sup>1</sup>. | Rifampin: Concomitant use contraindicated; consider alternative antimycobacterial (e.g., rifabutin); do not initiate ritonavir-boosted nirmatrelvir immediately after discontinuation of rifampin due to delayed offset of rifampin<sup>1</sup>. |
<table>
<thead>
<tr>
<th>Drug</th>
<th>Interaction</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Antineoplastic agents</td>
<td>Apalutamide: Possible decreased systemic exposure to nirmatrelvir and ritonavir, loss of virologic response, and development of nirmatrelvir resistance&lt;sup&gt;1&lt;/sup&gt;.</td>
<td>Apalutamide: Concomitant use contraindicated; do not initiate ritonavir-boosted nirmatrelvir immediately after discontinuation of apalutamide due to delayed offset of apalutamide&lt;sup&gt;1&lt;/sup&gt;.</td>
</tr>
<tr>
<td>(apalutamide, abemaciclib, ceritinib, dasatinib, encorafenib, ibrutinib, ivosidenib, neratinib, nilotinib, venetoclax, vinblastine, vincristine)</td>
<td>Ibrutinib, neratinib, venetoclacl: Possible increased antineoplastic concentrations&lt;sup&gt;1&lt;/sup&gt;.</td>
<td>Encorafenib, ibrutinib, ivosidenib, neratinib, venetoclax: Avoid concomitant use&lt;sup&gt;1&lt;/sup&gt;.</td>
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<tr>
<td>Antipsychotics</td>
<td>Potential for serious and/or life-threatening adverse effects (e.g., arrhythmia)&lt;sup&gt;1&lt;/sup&gt;.</td>
<td>Clozapine, lurasidone, pimozide: Concomitant use contraindicated&lt;sup&gt;1&lt;/sup&gt;. Quetiapine: If concomitant use with ritonavir-boosted nirmatrelvir is necessary, reduce quetiapine dosage and monitor for quetiapine adverse effects&lt;sup&gt;1&lt;/sup&gt;.</td>
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<tr>
<td>(clozapine, lurasidone, pimozide, quetiapine)</td>
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<tr>
<td>Antiretroviral agents, HIV protease inhibitors (PIs) (atazanavir, darunavir, fosamprenavir, indinavir, nelfinavir, saquinavir, tipranavir)</td>
<td>Possible increased systemic exposure to the HIV PI&lt;sup&gt;1&lt;/sup&gt;.</td>
<td>In patients currently receiving a ritonavir- or cobicistat- boosted HIV regimen, continue treatment as indicated and monitor for increased ritonavir or nirmatrelvir adverse events&lt;sup&gt;1&lt;/sup&gt;.</td>
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<tr>
<td>Drug</td>
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<tr>
<td>Benzodiazepines (midazolam, triazolam)</td>
<td>Oral midazolam or triazolam: Possible increased midazolam or triazolam concentrations and potential for serious and/or life-threatening effects (e.g., prolonged or increased sedation or respiratory depression)¹.</td>
<td>Oral midazolam or triazolam: Concomitant use contraindicated¹. Parenteral midazolam: Use concomitantly with caution and in monitored setting where respiratory depression and/or prolonged sedation can be managed; consider reduced midazolam dosage, especially if multiple midazolam doses are given¹.</td>
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<td>Parenteral midazolam: Possible increased midazolam concentrations¹.</td>
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<tr>
<td>Bictegravir</td>
<td>Fixed combination of bictegravir, emtricitabine, and tenofovir alafenamide fumarate (BIC/FTC/TAF): Possible increased bictegravir concentrations¹.</td>
<td>Discontinue bictegravir for ≥36 hours prior to initiating ritonavir-boosted nirmatrelvir¹.</td>
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<tr>
<td>Bosentan</td>
<td>Possible increased bosentan concentrations¹.</td>
<td>Monitor for adequate clinical response to bosentan¹.</td>
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<tr>
<td>Bupropion</td>
<td>Possible decreased concentrations of bupropion and its active metabolite (hydroxybupropion)¹.</td>
<td>Use concomitantly with caution; clinical monitoring recommended¹. If concomitant use cannot be avoided, dosage reduction of calcium-blocking agent may be necessary¹.</td>
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<tr>
<td>Calcium-channel blocking agents</td>
<td>Possible increased concentrations of the calcium-channel blocking agent¹.</td>
<td>Concomitant use contraindicated¹.</td>
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<tr>
<td>(amlodipine, diltiazem, felodipine, nicardipine, nifedipine)</td>
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<tr>
<td>Colchicine</td>
<td>Possible increased colchicine concentrations and potential for serious and/or life-threatening reactions in patients with renal and/or hepatic impairment¹.</td>
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<tr>
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<tr>
<td>Corticosteroids</td>
<td>Possible increased corticosteroid concentrations and increased risk of adrenal corticosteroid insufficiency or Cushing's syndrome&lt;sup&gt;1&lt;/sup&gt;. Consider alternative corticosteroid (e.g., beclomethasone, prednisolone)&lt;sup&gt;1&lt;/sup&gt;.</td>
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<tr>
<td>Dasabuvir</td>
<td>Possible increased HCV antiviral drug concentrations if used with fixed combination ombitasvir/paritaprevir/ritonavir/dasabuvir&lt;sup&gt;1&lt;/sup&gt;. In patients currently receiving a ritonavir-boosted HCV antiviral regimen, continue treatment as indicated and monitor for increased adverse effects of ritonavir-boosted nirmatrelvir or the HCV antiviral drug&lt;sup&gt;1&lt;/sup&gt;.</td>
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<tr>
<td>Delavirdine</td>
<td>Possible pharmacokinetic interaction&lt;sup&gt;1&lt;/sup&gt;.</td>
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<tr>
<td>Didanosine</td>
<td>Possible increased didanosine concentrations&lt;sup&gt;1&lt;/sup&gt;.</td>
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<tr>
<td>Digoxin</td>
<td>Possible increased digoxin concentrations&lt;sup&gt;1&lt;/sup&gt;. Use concomitantly with caution; monitor digoxin concentrations and adjust dosage as clinically indicated&lt;sup&gt;1&lt;/sup&gt;.</td>
<td></td>
</tr>
<tr>
<td>Efavirenz</td>
<td>Possible increased efavirenz plasma concentrations&lt;sup&gt;1&lt;/sup&gt;.</td>
<td></td>
</tr>
<tr>
<td>Elbasvir</td>
<td>Possible increased elbasvir concentrations and substantially increased grazoprevir concentrations if ritonavir-boosted nirmatrelvir used with fixed combination elbasvir/grazoprevir; increased grazoprevir concentrations may increase risk of increased ALT concentrations&lt;sup&gt;1&lt;/sup&gt;.</td>
<td></td>
</tr>
<tr>
<td>Emtricitabine</td>
<td>No effect on emtricitabine exposures if used with fixed combination of bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF)&lt;sup&gt;1&lt;/sup&gt;.</td>
<td></td>
</tr>
<tr>
<td>Ergot alkaloids</td>
<td>Potential for serious or life-threatening adverse effects (e.g., vasospasm, ischemia of extremities or other tissues)&lt;sup&gt;1&lt;/sup&gt;. Concomitant use contraindicated&lt;sup&gt;1&lt;/sup&gt;.</td>
<td></td>
</tr>
<tr>
<td>Drug</td>
<td>Interaction</td>
<td>Comments</td>
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<tr>
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</tr>
<tr>
<td>Estrogens</td>
<td>Oral hormonal contraceptives containing ethinyl estradiol: Possible decreased ethinyl estradiol concentrations(^1).</td>
<td>Use additional nonhormonal contraception methods(^1).</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>Possible increased fentanyl concentrations(^1).</td>
<td>Carefully monitor patient for fentanyl therapeutic and adverse effects, including potentially fatal respiratory depression(^1).</td>
</tr>
<tr>
<td>Glecaprevir and pibrentasvir</td>
<td>Increased HCV antiviral drug concentrations Concomitant use not if ritonavir-boosted nirmatrelvir is used with recommended(^1), fixed combination glecaprevir/pibrentasvir(^1).</td>
<td></td>
</tr>
<tr>
<td>Grazoprevir</td>
<td>Increased elbasvir concentrations and substantially increased grazoprevir concentrations if ritonavir-boosted nirmatrelvir is used with fixed combination elbasvir/grazoprevir; increased grazoprevir concentrations may increase risk of increased ALT concentrations(^1).</td>
<td></td>
</tr>
<tr>
<td>HMG-CoA reductase inhibitors (statins)</td>
<td>Lovastatin, simvastatin: Possible increased antilipemic concentrations and increased risk of statin-associated adverse effects, including myopathy and rhabdomyolysis(^1). Atorvastatin, rosuvastatin: Consider temporarily withholding atorvastatin and rosuvastatin during ritonavir-boosted nirmatrelvir therapy(^1), Lovastatin, simvastatin: Concomitant use with ritonavir-boosted nirmatrelvir contraindicated; discontinue lovastatin and simvastatin at least 12 hours prior to initiation of ritonavir-boosted nirmatrelvir(^1).</td>
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<tr>
<td>Drug</td>
<td>Interaction</td>
<td>Comments</td>
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<tr>
<td><strong>Immunosuppressive agents</strong></td>
<td><em>Cyclosporine, sirolimus, tacrolimus: Possible increased immunosuppressive</em></td>
<td><em>Cyclosporine, tacrolimus: Monitor plasma concentrations of immunosuppressive agent; avoid concomitant use if monitoring of immunosuppressive agent concentrations not feasible</em></td>
</tr>
<tr>
<td><em>(cyclosporine, sirolimus, tacrolimus)</em></td>
<td><em>agent concentrations&lt;sup&gt;1&lt;/sup&gt;.</em></td>
<td><em>Sirolimus: Avoid concomitant use</em>&lt;sup&gt;1&lt;/sup&gt;.</td>
</tr>
<tr>
<td><strong>Macrolides</strong></td>
<td>Possible increased macrolide concentration&lt;sup&gt;1&lt;/sup&gt;.</td>
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<tr>
<td><em>(clarithromycin, erythromycin)</em></td>
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<tr>
<td><strong>Maraviroc</strong></td>
<td>Possible increased maraviroc concentrations&lt;sup&gt;1&lt;/sup&gt;.</td>
<td></td>
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<tr>
<td><strong>Meperidine</strong></td>
<td>Possible increased meperidine concentrations and increased risk of serious respiratory depression or hematologic abnormalities&lt;sup&gt;1&lt;/sup&gt;.</td>
<td>Concomitant use contraindicated&lt;sup&gt;1&lt;/sup&gt;.</td>
</tr>
<tr>
<td><strong>Methadone</strong></td>
<td>Possible decreased methadone concentrations&lt;sup&gt;1&lt;/sup&gt;.</td>
<td>Closely monitor for opiate withdrawal since some patients may need adjustment of methadone maintenance dosage&lt;sup&gt;1&lt;/sup&gt;.</td>
</tr>
<tr>
<td><strong>Nevirapine</strong></td>
<td>Potential pharmacokinetic interaction&lt;sup&gt;1&lt;/sup&gt;.</td>
<td></td>
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<tr>
<td><strong>Ombitasvir</strong></td>
<td>Increased HCV antiviral drug concentrations *if ritonavir-boosted nirmatrelvir is used with receiving a ritonavir-boosted HCV antiviral regimen, continue ombitasvir/paritaprevir/ritonavir or ombitasvir/paritaprevir/ritonavir/dasabuvir&lt;sup&gt;1&lt;/sup&gt;, treatment as indicated and monitor for increased adverse effects of ritonavir-boosted nirmatrelvir or HCV antiviral drug&lt;sup&gt;1&lt;/sup&gt;.</td>
<td></td>
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<tr>
<td><strong>Paritaprevir</strong></td>
<td>Possible increased HCV antiviral drug concentrations if used with fixed combination ombitasvir/paritaprevir/ritonavir or ombitasvir/paritaprevir/ritonavir/dasabuvir&lt;sup&gt;1&lt;/sup&gt;, treatment as indicated and monitor for increased adverse effects of ritonavir-boosted nirmatrelvir or HCV antiviral drug&lt;sup&gt;1&lt;/sup&gt;.</td>
<td></td>
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<tr>
<td>Drug</td>
<td>Interaction</td>
<td>Comments</td>
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<tr>
<td>Piroxicam</td>
<td>Possible increased piroxicam concentrations and increased risk of serious respiratory depression or hematologic abnormalities&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Concomitant use contraindicated&lt;sup&gt;1&lt;/sup&gt;</td>
</tr>
<tr>
<td>Raltegravir</td>
<td>Possible decreased plasma concentrations of raltegravir&lt;sup&gt;1&lt;/sup&gt;</td>
<td></td>
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<tr>
<td>Ranolazine</td>
<td>Possible increased ranolazine concentrations and increased risk of serious and/or life-threatening adverse effects&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Concomitant use contraindicated&lt;sup&gt;1&lt;/sup&gt;</td>
</tr>
<tr>
<td>St. John’s wort&lt;sup&gt;1&lt;/sup&gt; (Hypericum perforatum)</td>
<td>Possible decreased nirmatrelvir and ritonavir concentrations, and possible loss of virologic response and development of resistance&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Concomitant use contraindicated; do not initiate ritonavir-boosted nirmatrelvir immediately after discontinuation of St. John’s wort due to delayed offset of St. John’s wort&lt;sup&gt;1&lt;/sup&gt;</td>
</tr>
<tr>
<td>Salmeterol</td>
<td>Possible increased salmeterol concentrations and increased risk of QT interval prolongation, palpitations, and sinus tachycardia&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Salmeterol (Revatio&lt;sup&gt;®&lt;/sup&gt;) for treatment of pulmonary arterial hypertension (PAH): Concomitant use with ritonavir-boosted nirmatrelvir contraindicated&lt;sup&gt;1&lt;/sup&gt;</td>
</tr>
<tr>
<td>Sildenafil</td>
<td>Possible increased sildenafil concentrations and increased risk of sildenafil-associated adverse effects (e.g., hypotension, visual disturbances, prolonged erection, syncope)&lt;sup&gt;1&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>Sofosbuvir</td>
<td>Possible increased sofosbuvir/velpatasvir/voxilaprevir concentrations if ritonavir-boosted nirmatrelvir is used with fixed combination of sofosbuvir, velpatasvir, and voxilaprevir (sofosbuvir/velpatasvir/voxilaprevir)&lt;sup&gt;1&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>Tenofovir alafenamide</td>
<td>Fixed combination of bictegravir, emtricitabine, and tenofovir alafenamide fumarate (BIC/FTC/TAF): Possible increased TAF concentrations if used with ritonavir-boosted nirmatrelvir&lt;sup&gt;1&lt;/sup&gt;</td>
<td></td>
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<tr>
<td>Trazodone</td>
<td>Possible increased trazodone concentrations Consider reduced trazodone dosage&lt;sup&gt;1&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>Velpatasvir</td>
<td>Possible increased sofosbuvir/velpatasvir/voxilaprevir concentrations if ritonavir-boosted nirmatrelvir is used with fixed combination of sofosbuvir, velpatasvir, and voxilaprevir (sofosbuvir/velpatasvir/voxilaprevir)&lt;sup&gt;1&lt;/sup&gt;</td>
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<tr>
<td>Drug</td>
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</tr>
<tr>
<td>Voxilaprevir</td>
<td>Possible increased sofosbuvir/velpatasvir/voxilaprevir concentrations if ritonavir-boosted nirmatrelvir is used with fixed combination of sofosbuvir, velpatasvir, and voxilaprevir (sofosbuvir/velpatasvir/voxilaprevir)</td>
<td>1.</td>
</tr>
<tr>
<td>Zidovudine</td>
<td>Possible decreased plasma concentrations of zidovudine</td>
<td>4.</td>
</tr>
</tbody>
</table>

### Pharmacokinetics

#### Absorption

Following oral administration of *ritonavir-boosted* nirmatrelvir, systemic exposure of nirmatrelvir increases in a less than dose proportional manner up to 750 mg (single dose) and up to 500 mg twice daily. Following administration of *ritonavir-boosted* nirmatrelvir twice daily for 10 days, steady-state concentrations of nirmatrelvir are attained on day 2 with approximately 2-fold accumulation.1

Following oral administration of a single 300-mg dose of nirmatrelvir with 100 mg of ritonavir in healthy individuals, peak plasma concentrations of nirmatrelvir and ritonavir are achieved in 3 and 3.98 hours, respectively.1

*Food*

Following coadministration of a suspension formulation of nirmatrelvir and ritonavir tablets with a high fat meal, mean peak plasma concentrations increased by approximately 15% and mean AUC increased by 1.6% relative to administration in a fasted state.1

#### Distribution

*Nirmatrelvir*: Not known whether nirmatrelvir is distributed into human or animal milk.1

*Ritonavir*: Limited published data indicate that ritonavir is present in human milk.1

Nirmatrelvir or ritonavir is 69 or 98–99% bound to plasma proteins, respectively.1

#### Elimination

Nirmatrelvir is a CYP3A4 substrate but metabolic clearance is minimal when coadministered with ritonavir.1 Ritonavir is primarily metabolized by CYP3A4 and, by a lesser extent, CYP2D6.1

*Nirmatrelvir*: Following a single 300-mg dose of nirmatrelvir administered in conjunction with 100 mg of ritonavir, mean elimination half-life of nirmatrelvir is 6.05 hours in healthy individuals.1

*Ritonavir*: Following a single 300-mg dose of nirmatrelvir administered in conjunction with 100 mg of ritonavir, mean elimination half-life of nirmatrelvir is 6.15 hours in healthy individuals.1
Following oral administration of a radiolabeled dose of nirmatrelvir suspension and ritonavir, 49.6% of the nirmatrelvir dose recovered in feces and 35.3% of the dose recovered in urine.¹

**Specific Populations**

Effects of age and sex on the pharmacokinetics of *ritonavir-boosted* nirmatrelvir not established.¹

Pharmacokinetics of *ritonavir-boosted* nirmatrelvir not evaluated in pediatric patients.¹

Based on adults with similar body weight to pediatric patients weighing ≥40 kg in the EPIC-HR clinical trial, the EUA-recommended dosage of *ritonavir-boosted* nirmatrelvir is expected to result in plasma concentrations in patients ≥12 years of age weighing ≥40 kg that are comparable to those observed in adults.¹

Systemic exposure is decreased in Japanese individuals compared with individuals from Western countries; however, the difference is not clinically significant.¹

**Stability**

**Storage**

**Oral**

**Tablets.**

Blister packs containing nirmatrelvir and ritonavir tablets: 20–25°C (excursions permitted between 15–30°C).¹

**Actions**

Nirmatrelvir is a peptidomimetic inhibitor of the SARS-CoV-2 main protease (Mpro) (also referred to as 3C-like protease [3CLpro] or nsp5 protease).¹

Following binding of nirmatrelvir directly to the SARS-CoV-2 Mpro active site, inhibition of SARS-CoV-2 Mpro prevents viral replication.¹

Nirmatrelvir had similar cell culture antiviral activity (EC₅₀ values 3-fold or less relative to USA-WA1/2020) against SARS-CoV-2 isolates belonging to the Alpha (B.1.1.7), Beta (B.1.351), Gamma (P.1), Delta (B.1.617.2), and Lambda (C.37) variants.¹

No data available regarding activity of nirmatrelvir against the SARS-CoV-2 Omicron (B.1.1.529) variant in cell culture.¹ In a biochemical assay, the Mpro P132H substitution found in the Omicron variant did not reduce nirmatrelvir activity compared to the USA-WA1/2020 enzyme.¹

Limited SARS-CoV-2 sequencing data are available to characterize nirmatrelvir resistance in clinical trials.¹ The SARS-CoV-2 Mpro substitutions A260V or A260T emerged in 4% (4/97) of patients receiving *ritonavir-boosted* nirmatrelvir in the EPIC-HR clinical trial with available sequence analysis data.¹

Cross-resistance not expected between nirmatrelvir and anti-SARS-CoV-2 monoclonal antibodies or remdesivir.¹
Advice to Patients

The following information contains important points for the clinician to discuss with patients during counseling. For more comprehensive monographs suitable for distribution to the patient, please refer to the AHFS Patient Medication Information monographs available from MedlinePlus (https://vsearch.nlm.nih.gov/vivisimo/cgi-bin/query-meta?v:project=medlineplus&query=Nirmatrelvir) (in English and Spanish; written at a 6th- to 8th-grade reading level).

The Fact Sheet for Patients, Parents, and Caregivers: Emergency Use Authorization (EUA) of Paxlovid for the Treatment of Coronavirus Disease 2019 (COVID-19) must be provided to patients or parent/caregivers prior to administration of ritonavir-boosted nirmatrelvir.1, 2
Inform patients or parent/caregivers that FDA authorized the emergency use of nirmatrelvir, which is an investigational drug that has not received FDA approval, for use in certain adults and pediatric patients with mild to moderate COVID-19 who are at high risk for progression to severe COVID-19, including hospitalization or death.1, 2
Inform patients or parent/caregivers about the significant known and potential risks and benefits of ritonavir-boosted nirmatrelvir, and the extent to which such risks and benefits are unknown.1
Advise patients treated with ritonavir-boosted nirmatrelvir that they should continue to self-isolate according to public health recommendations during the 5-day treatment course to maximize viral clearance and minimize transmission of SARS-CoV-2.1
Advise females of reproductive potential that ritonavir may decrease the effectiveness of hormonal contraceptives and that an effective alternative contraceptive method or an additional barrier method should be used during treatment.1
Importance of informing clinicians of existing or contemplated concomitant therapy, including prescription and OTC drugs and herbal supplements, as well as any concomitant illnesses.1
Importance of women informing clinicians if they are or plan to become pregnant or plan to breast-feed.2

Preparations

Excipients in commercially available drug preparations may have clinically important effects in some individuals; consult specific product labeling for details.

Nirmatrelvir is not commercially available.1 FDA issued an emergency use authorization (EUA) for ritonavir-boosted nirmatrelvir that allows use of the drug for the treatment of mild to moderate COVID-19 in certain adults and pediatric patients who are at high risk for progression to severe COVID-19, including hospitalization or death.1 The manufacturer (Pfizer) should be contacted for information on how to obtain ritonavir-boosted nirmatrelvir for use under the EUA.1

Nirmatrelvir with Ritonavir (https://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm?sugg=NonProprietaryName&ApptName=Nirmatrelvir&collapse=1)

Oral

Kit
20 Tablets, nirmatrelvir 150 mg
10 Tablets, ritonavir 100 mg

**Paxlovid™** *(each carton contains a total of 30 tablets divided in 5 daily-dose blister cards), Pfizer (https://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm? sugg=LabelerName&ApptName=Pfizer&collapse=1)*

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**Related Resources**

AHFS Patient Medication Information (https://vsearch.nlm.nih.gov/vivisimo/cgi-bin/query-meta?v:project=medlineplus&query=Nirmatrelvir) and other related patient health topics (MedlinePlus)
ASHP Drug Shortages Resource Center (https://www.ashp.org/Drug-Shortages)
CCRIS (https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+ccris:%22Nirmatrelvir%22) (Chemical Carcinogenesis Research Information System)
Biochemical Data Summary (http://www.drugbank.ca/unearth/q?utf8=%E2%9C%93&query=Nirmatrelvir&searcher=drugs&approved=1&vet_approved=1&nutraceutical=1&country=US and Canada)
Clinical Trials (https://www.clinicaltrials.gov/ct2/search?term=Nirmatrelvir&search_type=WMT)
DART (https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+dart:%22Nirmatrelvir%22) (Developmental and Reproductive Toxicology Database)
Drugs@FDA (https://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.SearchAction&SearchType=BasicSearch&SearchTerm=Nirmatrelvir) (approval information)
Inxight Drugs (https://drugs.ncats.io/substances?q=%22Nirmatrelvir%22) (National Center for Advancing Translational Sciences)
LactMed (drug effects on breastfeeding) (https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+lactmed:@or+%28@na+%22Nirmatrelvir%22+%29)
New Drug Approvals (http://ahfs.ashp.org/drug-assignments.aspx)
PharmGKB (https://www.pharmgkb.org/search?connections&gaSearch=Nirmatrelvir&query=Nirmatrelvir&type=chemical) (Pharmacogenomic data from PharmGKB)
References


ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's nearly 55,000 members include pharmacists, student pharmacists, and pharmacy technicians. For more than 75 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety. For more information about the wide array of ASHP activities and the many ways in which pharmacists advance healthcare, visit ASHP's website (https://www.ashp.org), or its consumer website (https://www.safemedication.com).

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