



Nirmatrelvir plus Ritonavir (Paxlovid®)

Adult (18 years and over)

Informed consent: patient information

(Affix identification label here)

URN:

Family name:

Given name(s):

Address:

Date of birth:

Sex: M F I

A copy of this patient information sheet should be given to the patient/substitute decision-maker to read carefully and allow time to ask any questions about the treatment. A copy should be included in the patient's medical record.

What is nirmatrelvir plus ritonavir (Paxlovid®) and how will it help me/the patient?

This treatment uses two drugs, nirmatrelvir and ritonavir, with the brand name Paxlovid®, taken together to treat COVID-19. Nirmatrelvir is an antiviral medication that blocks the ability of the virus from being able to make more copies of itself. Ritonavir boosts the amount of nirmatrelvir in the body so it has enough time to fight the virus. These medications need to be taken together.

In Australia, Paxlovid® is provisionally approved by the Therapeutic Goods Administration (TGA) for the treatment of COVID-19 in adults 18 years of age and older, **within 5 days of symptom onset**, who are not using oxygen and are at risk of becoming seriously ill or dying.

Paxlovid® is currently being studied. Interim trial data has helped inform the guidelines of the National COVID-19 Clinical Evidence Taskforce, which were used to create this patient information.

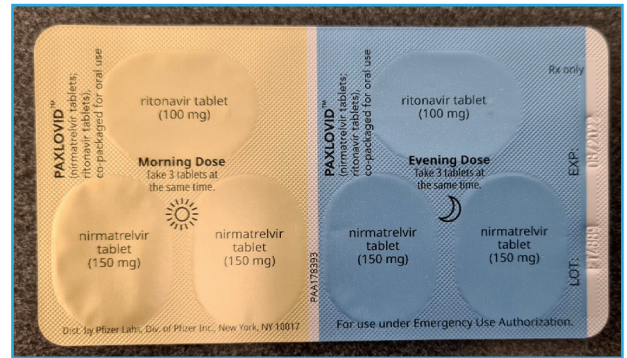


Image: Paxlovid® medication. Pharmacy Department, Royal Brisbane & Women's Hospital, 2022.

Preparing for the treatment

A doctor will discuss the risks and benefits of treatment with you and must obtain consent before it is given. The doctor will need to know about:

- any existing medical conditions
- any previous allergies to medications
- all medications, including over the counter or complementary medications that you have been taking
- the possibility that you are pregnant or have plans for a future pregnancy
- whether you are breastfeeding
- any recent vaccinations or plans for COVID-19 vaccinations and boosters.

Because this is a new medicine, information about how well it works and its safety is still being monitored. It has provisional Therapeutic Goods Administration (TGA) approval. It is important that you understand when and why Paxlovid® may be useful. Your doctor will discuss with you about how well it works and how safe it is in your condition.

What should I know before I take nirmatrelvir plus ritonavir?

Fertility

For Paxlovid® there are no research data in humans, but animal studies showed no risk to fertility.

Pregnancy

There are no research data about the effect of Paxlovid® in pregnant humans, and at very high doses in animals there was some risk (although this was not seen at lower doses). If there is a chance you could be pregnant, you should talk to your doctor about having a pregnancy test before taking Paxlovid®. You should use a reliable method of contraception (birth control) or not have sex **while taking Paxlovid® and for 7 days after the last dose** (some methods of contraception need to be taken until the next period if you do not want to become pregnant). Please seek advice from your general practitioner if needed.

Breastfeeding

There are no research data in humans about the effect of nirmatrelvir in breastmilk, effects on the infant, or effects on milk production. Ritonavir may pass into breastmilk, though effects on the infant are unknown. Breastfeeding is not recommended during treatment and for **7 days after the last dose of Paxlovid®**.



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How do I take Paxlovid®?

Paxlovid® is given as tablets, taken twice a day for 5 days. The usual dose is 2 pink tablets of nirmatrelvir, and 1 white tablet of ritonavir taken at the same time (i.e. 3 tablets) in the morning and the evening. These tablets can be taken with or without food and should be swallowed whole.

For people with kidney impairment a lower dose may be used.

What if I forget to take a dose?

You should take Paxlovid® regularly at the same times each day. It is important that you do not miss or skip doses of this medicine. If you do miss a dose:

- if it has been less than 8 hours since you were meant to take the dose, take it as soon as you remember
- if it has been more than 8 hours since you were meant to take the dose, skip the missed dose and take your next dose at scheduled time.

Do not take a double dose to make up for the dose you missed. Call your doctor or pharmacist if you are not sure what to do.

What are the risks of taking Paxlovid®?

Before you take Paxlovid®, tell the healthcare professional if you:

- have any allergies
- have any liver or kidney problems
- are pregnant or breastfeeding
- are living with HIV (should not be used if you have HIV but are currently not being treated)
- take any other medications.

All medicines have side effects. Sometimes they are serious, but most of the time they are not. It can also be hard to tell if the side effects are from the medication or are symptoms of COVID-19. This is a new medication and information about side effects will continue to be reviewed.

Paxlovid® can interact with other medications – it is vital that you tell the healthcare professionals any medications you are taking so they can check for drug interactions. Drug interactions can be significant as they can mean that you have too much of a medication in your system, or not enough. If you start a new medication while taking Paxlovid® – let a healthcare professional know.

These drug interactions may also mean that you need additional monitoring or have to make some changes to your regular medications. Your healthcare professionals can tell you if any of your regular medications need to change, and after you finish Paxlovid®, when it should change back (usually around 5 days).

A list of medications that should NOT be taken with Paxlovid® is provided at the end of this information sheet. If you are on any of these, it is generally advised that you do not take Paxlovid®.

Safety information has been assessed, showing that most side effects reported by patients were mild. Only 2.1% of people taking Paxlovid® stopped the medication due to a side effect.¹

Possible side effects of nirmatrelvir plus ritonavir

Tell the doctor or nurse if these symptoms occur:

- mild skin redness or rash (hives)
- diarrhoea
- altered sense of taste
- muscle aches
- high blood pressure
- liver problems (loss of appetite, yellowing of skin and yellowing of the whites of the eye, dark-coloured urine, pale-coloured stools, itchy skin, stomach pain).

Severe allergic reactions may occur, symptoms may include:

- feeling short of breath, wheezing, difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- severe skin rash including itching, blisters or ulcers in the mouth.

If symptoms of a severe allergic reaction occur, call an ambulance and immediately go to the nearest hospital.

It is possible (although unlikely) that other unknown side effects may occur with Paxlovid®. Side effects should be reported to the doctor directly. Your doctor or healthcare provider will report the details of the reaction to the Therapeutic Goods Administration (TGA) and document this in your medical record.

What are the risks of not having Paxlovid®?

Paxlovid® is used for the early treatment of COVID-19 in high-risk patients with other medical conditions to prevent progression to severe illness or death and reduce the need for hospitalisation. Your doctor can explain what high risk means. The decision to receive Paxlovid® will depend on your age, existing medical conditions and if you are vaccinated against COVID-19. Your doctor will discuss your health circumstances with you and any related risks.

In the results released from the EPIC-HR study, the group of patients who received Paxlovid® were 89% less likely to go to hospital or die compared to the group of patients who did not have Paxlovid®.¹

If you provided consent, you have the right to change your mind at any time. Please contact the doctor/clinician to discuss.

Are there alternative treatments?

There are other medications that can be used for COVID-19. Some are infusions and some are tablets. Your doctor will discuss the best option for you based on your health conditions, availability of the medications and your preferences.

What should I expect after treatment?

Delayed allergic reactions are rare but can still happen, so it is important that anyone who receives Paxlovid® watches themselves carefully for any side effects. Any concerns should be reported to the doctor or nurse immediately.

Some patients may still develop severe COVID-19 after Paxlovid®. It is important that you monitor your symptoms. If you start to feel unwell or your symptoms are worse but not serious – call 13 HEALTH (13 43 25 84). If you have serious symptoms, like difficulty breathing – call 000 and ask for an ambulance.

When can I get vaccinated?

Having Paxlovid® **won't affect** when your next vaccination is scheduled after you recover from COVID-19.

Where can I find support or more information?

- If you start to feel unwell or your symptoms are worse but not serious – **call 13 HEALTH (13 43 25 84)**.
- If you have serious symptoms, like difficulty breathing – **call 000 and ask for an ambulance**.
- Medication for treating COVID-19. Health Direct – Free Australian health advice you can count on. www.healthdirect.gov.au/covid-19-medication.

- National COVID-19 Clinical Evidence Taskforce. Australian Guidelines for the Clinical Care of people with COVID-19. <https://covid19evidence.net.au/#living-guideline>.
- Pfizer Australia Pty Ltd. Australian Consumer Medicines Information Paxlovid®. Therapeutic Goods Administration. Published January 2022. www.tga.gov.au/sites/default/files/paxlovid-cmi.pdf.

References:

1. Pfizer. Paxlovid® [product information]. Australian TGA website. Available from: www.tga.gov.au/sites/default/files/paxlovid-pi.pdf. Revised 20/1/22. Accessed 4/2/2022.

Medications that should NOT be taken with Paxlovid®

Class	Drug
Antiarrhythmics (for abnormal heartbeats)	amiodarone, flecainide, disopyramide, quinidine
Anticoagulants or antiplatelets (blood thinners)	apixaban, dabigatran, clopidogrel, rivaroxaban, ticagrelor
Anticonvulsants (for epilepsy)	carbamazepine, phenobarbital, phenytoin, primidone
Antidepressants	St John's wort
Anti-gout medications	colchicine
Antimicrobials (antibiotics)	rifampicin, rifapentine, fusidic acid
Antipsychotics (mental health medication)	lurasidone, clozapine, quetiapine
Benzodiazepines (to help calm the nervous system)	clonazepam, diazepam, midazolam
Bronchodilators (for making breathing easier)	salmeterol
Cancer chemotherapy/immunotherapy/targeted therapy	neratinib, veneoclax, apalutamide
Cardiac drugs (for the heart)	ranolazine, bosentan, eplerenone, ivabradine, lercanidipine
Ergot derivatives (for severe headache)	ergometrine, dihydroergotamine
Gastrointestinal drugs (for the stomach and bowel)	cisapride, domperidone
Hepatitis C antivirals (Hepatitis C medication)	elbasavir/grazoprevir, glecaprevir/pibrentasvir
HMG-CoA reductase inhibitors (for cholesterol)	lovastatin, simvastatin
Immunosuppressants (for slowing down the immune system)	ciclosporin, everolimus, sirolimus, tacrolimus
Pain medication	pethidine, piroxicam, dextropropoxyphene
PDE5 inhibitors (for erectile dysfunction or lung disease)	avanafil, sildenafil, vardenafil, tadalafil
Prostate gland enlargement	alfuzosin

Many other medications interact with Paxlovid® and may mean that you can't safely take this drug. Your healthcare professional must check for drug interactions with Paxlovid® against every medication you are taking, including over the counter and complementary medicines.