



PAXLOVID®

Patient Information

This information leaflet includes important information about the medicine called **Paxlovid®** when used in the treatment of COVID-19. Having COVID-19 infection and being treated does not offer the same protection as vaccination.

What is the medication used for?

Paxlovid® has been provisionally registered by the Therapeutic Goods Administration in Australia to treat adults with COVID-19 who do not need oxygen but are at risk of severe illness and hospitalisation. This medicine is not intended to be a replacement for vaccination against COVID-19.

Paxlovid® is used in adults to treat mild to moderate coronavirus disease (COVID-19) in patients:

- who have a positive result from a severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral test, AND
- who have a high risk of getting severe COVID-19, including hospitalisation or death.

Paxlovid® must not be used:

- to treat patients with severe or critical COVID-19 infection
- to treat patients who have had symptoms for more than 5 days
- as a preventive medicine to stop COVID-19 infection from occurring
- for longer than 5 days in a row
- to treat children and adolescents less than 18 years of age.

Do not give your medicine to anyone else, even if they have the same condition as you.

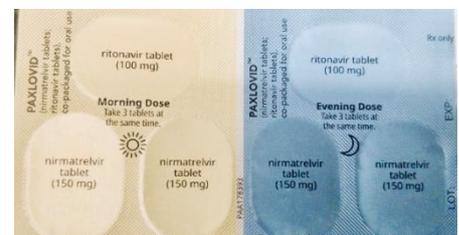
What does this medication do?

COVID-19 is caused by a virus called a coronavirus. Paxlovid® contains 2 antiviral medicines that are co-packaged together, nirmatrelvir and ritonavir.

Paxlovid® stops the virus from multiplying. This can help your body to overcome the virus infection and may help you to get better faster.

Paxlovid® consists of 2 medicines co-packaged together:

- **Nirmatrelvir (pink tablet):** 150 mg
- **Ritonavir (white tablet):** 100 mg



What should be considered when using Paxlovid® for COVID-19?

Paxlovid® is a new medicine so information about how well it works and how safe it is, is being collected.

It is important that patients and their carers understand when and why Paxlovid® may be useful. Your health practitioner will provide more information about how well it works and how safe it is for your condition.

The use of Paxlovid® for COVID-19 is new and it is important for you to provide your formal consent before Paxlovid® treatment begins. You can always change your mind about treatment with Paxlovid® and withdraw your consent at any time.

How do you store the medication?

Store at room temperature (15°C to 30°C) away from sunlight, excessive heat and moisture. Keep out of reach and sight of children and pets.

How should this medication be used?

- Paxlovid® consists of 2 medications: nirmatrelvir and ritonavir.
- Take 2 pink tablets of nirmatrelvir with 1 white tablet of ritonavir by mouth twice a day, in the morning and at bedtime, for 5 days. Take all 3 tablets at the same time
- You must always take the nirmatrelvir tablets at the same time as the ritonavir tablet.
- If you have kidney problems, you may need to take a lower dose. Check with your health practitioner.
- You can take Paxlovid® with or without food. Swallow the tablets whole. Do not break, chew or crush the tablets.
- Even if you feel better, it is important to take the full 5-day treatment course. Do not stop taking Paxlovid® without talking to your health practitioner first.
- Talk to your health practitioner if you do not feel better or if you feel worse after 5 days.

Pharmacist or health practitioner to tick relevant regimen.

STANDARD DOSE – Take 2 pink tablets of nirmatrelvir with 1 white tablet of ritonavir by mouth every 12 hours at the same time each morning and evening. Use this calendar to help keep track of your doses. Note, if your first dose was in the evening on Day 1 your last dose may be in the morning on Day 6.

What should the health practitioner know before Paxlovid® is used in COVID-19?

The health practitioner should know about:

- any medical conditions you have
- previous allergic reactions to any medicine
- all medicines including over-the-counter and complementary medicines e.g. vitamins, minerals, herbal or naturopathic medicines that you are taking or have recently taken
- the possibility of pregnancy or plans for pregnancy
- recent vaccinations or plans to get vaccinated

| | Day 1 | Day 2 | Day 3 | Day 4 | Day 5 |
|--|----------------|----------------|----------------|----------------|----------------|
| | Date: | Date: | Date: | Date: | Date: |
| Morning  2 x nirmatrelvir 1 x ritonavir Time: | | | | | |
| Evening  2 x nirmatrelvir 1 x ritonavir Time: | | | | | |

REDUCED DOSE (if you have reduced kidney function) – Take one (1) pink tablet of nirmatrelvir with one (1) white tablet of ritonavir by mouth every 12 hours at the same time each morning and evening. **The pharmacy will modify the packaging of the medication to ensure you have the correct number of tablets for your dose.** Use this calendar to help keep track of your doses. Note, if your first dose was in the evening on Day 1 your last dose may be in the morning on Day 6.

| | Day 1 | Day 2 | Day 3 | Day 4 | Day 5 |
|--|----------------|----------------|----------------|----------------|----------------|
| | Date: | Date: | Date: | Date: | Date: |
| Morning  1 x nirmatrelvir 1 x ritonavir Time: | | | | | |
| Evening  1 x nirmatrelvir 1 x ritonavir Time: | | | | | |

What should you do if you forget a dose?

- If it has been less than 8 hours since the missed dose, take the dose as soon as you remember.
- If it has been more than 8 hours since the missed dose, skip this dose and take your dose at the next scheduled time.
- Do not double the dose to make up for a missed dose.

What should you do if you take too much?

If you think you, or a person you are caring for, has taken too much Paxlovid®, you may need urgent medical attention.

You should immediately:

- contact your health practitioner OR
- phone the Poisons Information Centre (13 11 26), OR
- go to the emergency department of your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

What are some common side effects?

Paxlovid® is generally well tolerated – most people only experience mild side effects.

Rarely, Paxlovid® may cause liver problems, or resistance to HIV medications if you have untreated HIV infection.

Some other reported side effects include:

- altered sense of taste or metallic taste in mouth
- vomiting or diarrhea
- high blood pressure
- muscle aches
- headaches
- nausea
- abdominal pain

Unwanted side effects are possible with all medications. The effects listed are not all of the side effects that can occur.

If you have a troublesome symptom or side effect that is not listed here or becomes severe enough to interfere with your daily activities, tell your health practitioner.

Speak with your healthcare provider if you have questions about side effects.

If you are experiencing any side effects, including any of the ones listed above or are feeling unwell in any way, please call the health practitioner on the phone number below for advice.

Name of health practitioner to call:

Telephone number:

Who should I know before I take Paxlovid®?

- **Do not take Paxlovid® if you are allergic to nirmatrelvir, ritonavir or to any of the other ingredients in Paxlovid®:**
 - Nirmatrelvir tablets: microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, colloidal silicon dioxide, sodium stearyl fumarate.
 - Ritonavir tablets: copovidone, calcium hydrogen phosphate, sorbitan monolaurate, hypromellose, colloidal anhydrous silica, titanium dioxide, sodium stearyl fumarate, macrogol 400, hypromellose, purified talc, macrogol 3350, polysorbate 80.
- **Tell your health practitioner if you are pregnant, think you might be pregnant or are planning to become pregnant.** You should not take Paxlovid® if you are pregnant. Women of childbearing potential should be on an effective contraceptive method before starting treatment and for 7 days after stopping treatment. Tell your doctor if you are pregnant or plan to become pregnant, breastfeeding or planning to breastfeed. Call your doctor straight away if you become pregnant while taking this medicine.
- Paxlovid® may affect how birth control pills, patches and vaginal rings work. You should use alternative contraception or an additional barrier method such as a condom while you are taking Paxlovid®. Talk to your health practitioner about effective methods of birth control.
- **Breastfeeding:** Paxlovid® consists of 2 medicines, nirmatrelvir and ritonavir. There is no data on the use of nirmatrelvir during breastfeeding and its properties make it unlikely that large amounts will pass into breast milk. Ritonavir is known to transfer into breastmilk. The blood levels of breastfed infants were low and there were no reported adverse effects. Use of Paxlovid® is not a reason to discontinue breastfeeding, however, it should only be used with careful infant monitoring during breastfeeding. For further information about the use of this medicine in pregnancy, breastfeeding or family planning, please contact the King Edward Memorial Hospital Obstetric Medicines Information Service on 6458 2723.

- **Patients with kidney problems:** Tell your health practitioner before you take Paxlovid® if you have any kidney problems. You might need a lower dose of Paxlovid®. Your health practitioner will prescribe a dose that is right for you.
- **Liver problems:** Before you take Paxlovid® tell your health practitioner if you have any liver problems. Liver problems have happened in patients taking ritonavir, a medicine in Paxlovid®. Talk to your health practitioner if you get any symptoms of liver problems. These may include yellow skin or whites of eyes, nausea, tiredness or feeling unwell, loss of appetite, fever, skin rash, abdominal pain, pale stool or dark coloured urine.
- **Paxlovid® interacts with many medications and herbal supplements.** Taking Paxlovid® with some medicines may cause serious or life-threatening side effects.

Let your doctor know if you are taking, or have recently taken, any of the following medicines as they should not be taken with Paxlovid®:

- **alfuzosin** - medicine to treat an enlarged prostate
- **pethidine, piroxicam** - medicines to relieve pain
- **amiodarone, flecainide** - medicines to correct or change heart rhythm or lower blood pressure
- **neratinib, apalutamide, venetoclax** - medicines to treat certain types of cancers
- **colchicine** - medicine to treat gout
- **lurasidone, clozapine** - medicines to treat certain mental and emotional health conditions
- **ergometrine** - medicine to stop excessive bleeding that may occur following childbirth, miscarriage or termination of pregnancy
- **simvastatin** - medicine to lower blood cholesterol
- **avanafil, vardenafil** - medicines for erectile dysfunction
- **sildenafil** - medicine for erectile dysfunction, or to treat high blood pressure in the lungs
- **tadalafil** - medicine for erectile dysfunction, or urinary difficulties due to an enlarged prostate
- **diazepam** - medicine to assist anxiety, agitation or muscle spasms
- **carbamazepine, phenobarbital, phenytoin** - medicines to treat epilepsy or prevent convulsions.
- **rifampicin** - medicine to treat tuberculosis
- **St. John's Wort** (*hypericum perforatum*) - a herbal remedy used for depression and anxiety.

- This is not a complete list of medicines that interact with Paxlovid®.
- Tell your healthcare professional about ALL of the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines
- You doctor will check they are suitable to take with Paxlovid®, as some medicines may need extra monitoring, a dose change or be stopped while you are taking Paxlovid®.
- Talk to your healthcare professional first before taking any new medicines while taking Paxlovid®. They will tell you if it is safe to take.

What should I do if my COVID-19 symptoms get worse?

Call your healthcare provider if you have any questions or concerns.

Call 000 immediately if you experience severe symptoms of COVID-19, such as:

- difficulty breathing
- severe chest pain
- feelings of disorientation or confusion
- loss of consciousness.

If you have any questions about this medication, call your health practitioner.

What should I do after I finish my treatment?

You are still considered to be contagious while you are taking this medicine. Follow all Public Health guidelines available on the Healthy WA website [[What to do when you test positive for COVID-19 \(healthywa.wa.gov.au\)](https://www.healthysa.gov.au/what-to-do-when-you-test-positive-for-covid-19)] for staying safe and keeping others safe while you are unwell.

This document can be made available in alternative formats on request for a person with disability.

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Adapted from The Government of Canada, *Drug Details: Paxlovid* <https://covid-vaccine.canada.ca/info/paxlovid-en.html>