PAXLOVID®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I taking PAXLOVID?

PAXLOVID is a medicine that has two different tablets; one containing the active ingredient, nirmatrelvir and the other containing the active ingredient, ritonavir.
PAXLOVID is used to treat COVID-19 in adults who are at increased risk of progression to hospitalisation or death.
For more information, see Section 1. Why am I taking PAXLOVID? in the full CMI.

2. What should I know before I take PAXLOVID?

Do not take if you have ever had an allergic reaction to PAXLOVID or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions or if you have reduced kidney or liver function. You must not take PAXLOVID with certain medicines because these medicines may cause serious or life-threatening side effects or affect how PAXLOVID works.

Tell your doctor if you are pregnant or plan to become pregnant, breastfeeding or planning to breastfeed. You should not be taking 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. You should not breastfeed your baby while taking PAXLOVID and for 48 hours after stopping treatment.

For more information, see Section 2. What should I know before I take PAXLOVID? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PAXLOVID and affect how it works.
A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I take PAXLOVID?

You doctor will decide how much PAXLOVID you will need to take. It will depend on whether you have kidney problems. Nirmatrelvir must be taken together with ritonavir.

More instructions can be found in Section 4. How do I take PAXLOVID? in the full CMI

5. What should I know while taking PAXLOVID?

Things you should do	If you are of childbearing age, you should be on an effective method of contraception while taking PAXLOVID and for 7 days after stopping treatment. Call your doctor straight away if you become pregnant while taking this medicine.
Things you should not do	Do not stop taking this medicine or change the dosage without checking with your doctor. Do not give your medicine to anyone else, even if they have the same condition as you.
Driving or using machines	There is no specific information on the effect of PAXLOVID on your ability to drive or use machines.
Looking after your medicine	Store PAXLOVID below 25°C.

For more information, see Section 5. What should I know while taking PAXLOVID? in the full CMI.

6. Are there any side effects?

Side effects may include diarrhoea, vomiting, headache, allergic reactions, high blood pressure, changes in taste or a metallic taste in the mouth, nausea, abdominal pain and generally feeling unwell.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

PAXLOVID®

Active ingredient(s): *nirmatrelvir and ritonavir*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking PAXLOVID. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking PAXLOVID.**

Where to find information in this leaflet:

1. Why am I taking PAXLOVID?
2. What should I know before I take PAXLOVID?
3. What if I am taking other medicines?
4. How do I take PAXLOVID?
5. What should I know while taking PAXLOVID?
6. Are there any side effects?
7. Product details

1. Why am I taking PAXLOVID?

PAXLOVID contains the active ingredients nirmatrelvir and ritonavir.

PAXLOVID is used to treat COVID-19 in adults who are at increased risk of progression to hospitalisation or death.

2. What should I know before I take PAXLOVID?

Warnings

Do not take PAXLOVID if:

- You are allergic to nirmatrelvir and/or ritonavir or any of the ingredients listed at the end of this leaflet.
- You are taking any of these medicines. Taking PAXLOVID with these medicines may cause serious or life-threatening side effects or affect how PAXLOVID work:
  - alfuzosin, silodosin, medicine to treat symptoms of an enlarged prostate
  - ranolazine, medicine to treat chronic chest pain (angina)
  - pethidine, medicine to relieve pain
  - amiodarone, flecainide, medicine to correct or change heart rhythm or lower blood pressure
  - neratinib, apalutamide, enzalutamide, venetoclax, medicine to treat certain types of cancers
  - colchicine, medicine to treat gout
  - lurasidone, clozapine, cariprazine, medicine to treat certain mental and emotional health conditions
  - eplerenone, ivabradine, medicine used to treat heart failure; eplerenone, medicine for high blood pressure
  - ergometrine, medicine to stop excessive bleeding that may occur following childbirth, miscarriage or termination of pregnancy
  - simvastatin, medicine to lower blood cholesterol
  - eletriptan, rimegepant, medicine used to treat migraine headaches
  - finerenone, medicine used to treat kidney disease and type 2 diabetes
  - naloxegol, medicine used to treat constipation
  - avanafil, vardenafil, when used for erectile dysfunction
  - sildenafil, when used to treat high blood pressure in the lungs
  - diazepam, medicine to assist anxiety, agitation or muscle spasms, spasticity
  - triazolam, zolpidem, medicine that works in the brain to help you sleep
  - tolvaptan, medicine used to treat kidney problems or low sodium levels in the blood
  - carbamazepine, phenobarbital, phenytoin, primidone, medicine to treat epilepsy to prevent convulsions, fits
  - rifampicin, medicine to treat tuberculosis
  - lumacaftor/ivacaftor, medicine used to treat cystic fibrosis
  - St. John's Wort (hypericum perforatum), a herbal remedy used for depression and anxiety.

Check with your doctor if you:

- Have or have had problems with your liver.
- Have or have had problems with your kidneys.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Tell your doctor if you become pregnant or plan to become pregnant, breastfeeding or plan to breast feed. You should not breastfeed your baby while taking PAXLOVID and for 48 hours after stopping treatment.

You should not be taking 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.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins, or supplements that you buy without a prescription from your pharmacy, supermarket, or health food shop.

Some medicines may cause serious or life-threatening side effects or affect how PAXLOVID work. These include:

- medicines listed in Section 2. What should I know before I take PAXLOVID?
- tamsulosin, medicine to treat symptoms of an enlarged prostate
- fentanyl, hydrocodone, oxycodone, methadone, piroxicam, medicine to treat pain
- digoxin, medicine to treat certain heart conditions
- lidocaine, disopyramide, medicine to correct or change heart rhythm
- mavacamten, medicine to treat heart disease with a thickened muscle in the heart
- afatinib, abemaciclib, ceritinib, dasatinib, nilotinib, encorafenib, ibrutinib, vinblastine, vincristine, medicine to treat certain types of cancer
- aripiprazole, brexpiprazole, haloperidol, risperidone, quetiapine, medicine to treat certain mental and emotional conditions
- apixaban, clopidogrel, dabigatran, rivaroxaban, ticagrelor, warfarin, medicine to treat or prevent blood clots
- clonazepam, lamotrigine, medicine to prevent or treat convulsions, fits
- amitriptyline, fluoxetine, imipramine, nortriptyline, paroxetine, sertraline, medicine to treat depression
- loratadine, medicine to treat allergies
- atovaquone, clarithromycin, erythromycin, rifabutin, ketoconazole, isavuconazonium sulfate, voriconazole, itraconazole, medicine to treat infections
- albendazole, medicine to clear worms or parasites from the gut
- atazanavir, darunavir, efavirenz, fosamprenavir, maraviroc, nevirapine, saquinavir, tipranavir, raltegravir, zidovudine, bictegravir/ emtricitabine/ tenofovir, medicine to treat HIV
- glecaprevir/pibrentasvir or sofosbuvir/ velpatasvir/ voxilaprevir, medicine to treat hepatitis C
- salmeterol, medicine to treat severe lung conditions, including asthma and chronic obstructive pulmonary disease (COPD)
- amlodipine, diltiazem, felodipine, nifedipine, verapamil, medicine to treat angina or lower blood pressure
- ivacaftor, elexacaftor/tezacaftor/ivacaftor, tezacaftor/ivacaftor, medicine used to treat cystic fibrosis
- saxagliptin, medicine used to lower blood sugar levels in patients with type 2 diabetes mellitus
- ethinylestradiol, medicine to treat hormone deficiency or for contraception
- ciclosporin, everolimus, tacrolimus, sirolimus, medicine to suppress the immune system
- tofacitinib, upadacitinib, medicine used to treat inflammatory conditions including rheumatoid arthritis, psoriatic arthritis or ulcerative colitis
- darifenacin, medicine used to decrease the urgency and the frequency of urination
- sildenafil, when used to treat erectile dysfunction
- tadalafil, medicine used to treat erectile dysfunction or high blood pressure in the lungs
- bosentan, riociguat, medicine to treat high blood pressure in the lungs
- atorvastatin, rosuvastatin, medicine to lower cholesterol
- alprazolam, midazolam, suvorexant, medicine to help you sleep
- buspirone, clorazepate, medicine used to treat anxiety, convulsions, fits or help you sleep
- bupropion, a medicine to assist in giving up smoking
- betamethasone, budesonide, ciclesonide, dexamethasone, fluticasone, methylprednisolone, mometasone, triamcinolone, medicine to treat various inflammatory conditions including allergies, asthma or eczema.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect PAXLOVID.

4. How do I take PAXLOVID?

How much to take

Your doctor will decide how much PAXLOVID you will need to take. It will depend on whether you have kidney problems.

The standard dose is two 150 mg tablets of nirmatrelvir together with one 100 mg tablet of ritonavir, twice daily for the 5 days of treatment.

If you suffer from moderately reduced kidney function, your doctor may tell you to only take one 150 mg tablet of nirmatrelvir with one 100 mg tablet of ritonavir, twice daily for the 5 days of treatment.

If you suffer from severely reduced kidney function, your doctor may tell you to take two 150 mg tablet of nirmatrelvir with one 100 mg tablet of ritonavir (once only) on the first day of treatment and only take one 150 mg tablet of nirmatrelvir with one 100 mg tablet of ritonavir (once a day) for the remaining 4 days of treatment. The tablets should be taken at the same time each day. If undergoing haemodialysis, the tablets should be taken after haemodialysis.

Nirmatrelvir and ritonavir tablets can be taken with or without food.

Nirmatrelvir must be taken together with ritonavir.

The tablets should be swallowed whole and not chewed, broken, or crushed.

When to take PAXLOVID

Take PAXLOVID tablets every 12 hours at about the same time each morning and evening. It will help you remember when to take it.

How to long to take PAXLOVID

PAXLOVID is to be taken for 5 days.

Continue taking PAXLOVID until you finish the pack or until your doctor recommends.

If you forget to take PAXLOVID

If you miss a dose of PAXLOVID within 8 hours of the time it is usually taken, take it as soon as you remember.

If you miss a dose by more than 8 hours, skip the missed dose and take the next dose at your regular time. Do not take 2 doses of PAXLOVID at the same time.

If you take too much PAXLOVID

If you think that you have taken too much PAXLOVID, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

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

5. What should I know while taking PAXLOVID?

Things you should do

Tell your doctor if you become pregnant or plan to become pregnant, are breastfeeding or plan to breast feed. Call your doctor straight away if you become pregnant while taking this medicine.

Things you should not do

Do not stop taking this medicine or change the dosage without consulting with your doctor.

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

Driving or using machines

Be careful before you drive or use any machines or tools until you know how PAXLOVID affects you.

Drinking alcohol

No information is available

Looking after your medicine

Store PAXLOVID below 25°C.

Store it in a cool dry place away from moisture, heat, or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Do not take this medicine after the expiry date.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects

Side effects	What to do
• Vomiting • Diarrhoea • Headache • High blood pressure • Changes in taste or a metallic taste in the mouth • Nausea • Abdominal pain • Generally feeling unwell.	**Speak to your doctor if you have any of these side effects and they worry you.**
• Severe allergic reaction, including raw, painful and/or peeling of the skin, blisters, sore throat or mouth, or fever. • Signs and/or symptoms of an allergic reaction, including rash, itch, development of hives, swelling of the face (or of the tongue, lips, eyes, throat), feeling breathless, light-headed or dizzy, and feeling unwell.	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

What PAXLOVID contains

Nirmatrelvir tablet

Active ingredient (main ingredient)	Nirmatrelvir
Other ingredients (inactive ingredients)	Microcrystalline cellulose Lactose monohydrate Croscarmellose sodium

	Colloidal silicon dioxide Sodium stearylfumarate Opadry Complete Film Coating System 05B140011 Pink.

Ritonavir tablet

Active ingredient (main ingredient)	Ritonavir
Other ingredients (inactive ingredients)	Copovidone Calcium hydrogen phosphate Sorbitan monolaurate Hypromellose Colloidal anhydrous silica Titanium dioxide Sodium stearylfumarate Macrogol 400 Hyprolose Purified talc Macrogol 3350 Polysorbate 80

Do not take this medicine if you are allergic to any of these ingredients.

What PAXLOVID looks like

Nirmatrelvir tablet

- A pink, oval film-coated tablet debossed with ‘PFE’ on one side and ‘3CL’ on the other side.

Ritonavir tablet

- A white to off-white, film-coated, oval tablet debossed with "NK" on one side; or
- A white to off-white, capsule shaped, film-coated tablet, debossed with 'H' on one side and 'R9' on other side.

Pack size

- PAXLOVID is supplied in a carton of 30 tablets in five PA/Al/PVC/Al blister cards marked as "Morning Dose" and "Evening Dose" for the tablets to be taken each morning and each evening.

Australian Registration Number

PAXLOVID: AUST R 377572.

Who distributes PAXLOVID

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedinfo.com.au

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