

EMERGENCY USE AUTHORIZATION

Package leaflet: Information for the patient

Paxlovid 150 mg/100 mg film-coated tablets nirmatrelvir/ritonavir

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Paxlovid is and what it is used for
2. What you need to know before you take Paxlovid
3. How to take Paxlovid
4. Possible side effects
5. How to store Paxlovid
6. Contents of the pack and other information

1. What Paxlovid is and what it is used for

Paxlovid is an antiviral medicine used for treating mild-to-moderate COVID-19. COVID-19 is caused by a virus. Paxlovid stops the virus multiplying in cells and this stops the virus multiplying in the body. This can help your body to overcome the virus infection, and may help you get better faster.

Paxlovid contains the active substances nirmatrelvir and ritonavir. Nirmatrelvir is active against the virus that causes COVID-19. Ritonavir prolongs the therapeutic effect of nirmatrelvir.

Paxlovid is used in adults and adolescents 12 years of age and older and weighing at least 40 kg with mild-to-moderate COVID-19. It is only used in patients who do not require supplemental oxygen and who are at increased risk for progression to severe COVID-19, including hospitalisation or death.

You must talk to a doctor if you do not feel better or if you feel worse while on treatment with Paxlovid.

2. What you need to know before you take Paxlovid

Do not take Paxlovid

- if you are allergic to nirmatrelvir, ritonavir or any of the other ingredients of this medicine (listed in section 6).
- if you have severe liver or kidney disease.
- if you are taking any of the following medicines. Taking Paxlovid with these medicines may cause serious or life-threatening side effects or affect how Paxlovid works:
 - alfuzosin (used to treat symptoms of an enlarged prostate)
 - ranolazine (used to treat chronic chest pain [angina])
 - neratinib, venetoclax (used to treat cancer)
 - amiodarone, bepridil, dronedarone, encainide, flecainide, propafenone, quinidine (used to treat heart conditions and correct irregular heartbeats)

- fusidic acid (used to treat bacterial infections)
- colchicine (used to treat gout)
- astemizole, terfenadine (used to treat allergies)
- lurasidone, pimozide (used to treat schizophrenia)
- quetiapine (used to treat schizophrenia, bipolar disorder, severe depression and abnormal thoughts or feelings)
- silodosin (used to treat benign prostate enlargement)
- eplerenone, ivabradine (used to treat heart failure, a condition where the heart is unable to pump enough blood to other parts of the body)
- dihydroergotamine, ergotamine, eletriptan, ubrogepant (used to treat migraine headaches)
- ergonovine, methylergonovine (used to stop excessive bleeding that may occur following childbirth or an abortion)
- cisapride (used to relieve certain stomach problems)
- voclosporin (used to reduce a specific immune response)
- lovastatin, simvastatin, lomitapide (used to lower blood cholesterol)
- finerenone (used to treat chronic kidney disease)
- naloxegol (used to treat constipation in patients receiving opioid pain killers)
- avanafil, vardenafil (used to treat erectile dysfunction [also known as impotence])
- sildenafil (Revatio®) used to treat pulmonary arterial hypertension (high blood pressure in the pulmonary artery)
- triazolam, midazolam taken orally (used to relieve anxiety and/or trouble sleeping)
- flibanserin (used to treat low sexual desire in women who have not gone through menopause)
- tolvaptan (used to treat cysts in kidneys)
- carbamazepine, phenobarbital, phenytoin, primidone (used to prevent and control seizures)
- rifampicin (used to treat tuberculosis)
- lumacaftor/ivacaftor (used to treat cystic fibrosis)
- St. John's Wort (*Hypericum perforatum*) (a herbal remedy used for depression and anxiety)

Warnings and precautions

Allergic reactions

Allergic reactions, including severe allergic reactions (known as 'anaphylaxis') and serious skin reactions (known as toxic epidermal necrolysis and Stevens Johnson syndrome), can happen in people taking Paxlovid, even after only 1 dose. Stop taking Paxlovid and call your doctor right away if you get any of the following symptoms of an allergic reaction:

- trouble swallowing or breathing
- swelling of the tongue, mouth and face
- throat tightness
- hoarseness
- red and painful skin
- blisters and peeling skin
- blisters or sores in your mouth or lips

Risk of HIV-1 resistance development

If you have untreated or uncontrolled HIV infection, Paxlovid may lead to some HIV medicines not working as well in the future.

Liver disease

Tell your healthcare provider if you have or have had a liver disease. Do not take Paxlovid if you have severe liver disease.

Children and adolescents

Do not give Paxlovid to children under 12 years because Paxlovid has not been studied in children.

Other medicines and Paxlovid

There are other medicines that may not mix with Paxlovid. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including prescription and over-the-counter medicines, vitamins and herbal supplements.

Please tell your doctor if you are taking oral contraceptive pills as you may need to take extra contraceptive precautions such as using a condom (see below ‘Pregnancy, breast-feeding and fertility’).

In particular, you should inform your doctor or pharmacist if you are taking any of the following:

- medicines used to treat symptoms of an enlarged prostate, such as tamsulosin
- medicines used to treat attention disorders, such as amphetamine derivatives e.g. methylphenidate and dexamfetamine
- medicines used to treat severe pain, such as morphine, fentanyl, hydrocodone, oxycodone, meperidine, methadone, buprenorphine, norbuprenorphine and other morphine-like medicines
- medicines used to treat heart conditions and correct irregular heartbeats, such as digoxin and disopyramide
- medicines used to treat cancer, such as afatinib, abemaciclib, apalutamide, ceritinib, dasatinib, nilotinib, vincristine, vinblastine, encorafenib, fostamatinib, ibrutinib and ivosidenib
- medicines used to thin the blood (anticoagulants), such as warfarin, apixaban, dabigatran, rivaroxaban and vorapaxar
- medicines used to treat convulsions, such as divalproex and lamotrigine
- medicines used to treat depressions, such as amitriptyline, fluoxetine, imipramine, nortriptyline, paroxetine, sertraline and desipramine
- medicines used to treat allergies, such as fexofenadine and loratadine
- medicines used to treat fungal infections (antifungals), such as ketoconazole, itraconazole and voriconazole
- medicines used to treat bacterial infections (antibiotics and antimycobacterials), such as rifabutin, erythromycin, atovaquone, bedaquiline, delamanid, rifapentine, clarithromycin and sulfamethoxazole/trimethoprim
- medicines used to treat HIV infection, such as atazanavir, darunavir, efavirenz, maraviroc and zidovudine
- medicines used to treat mental or mood disorders, such as clozapine, haloperidol, risperidone, thioridazine, suvorexant, aripiprazole, brexpiprazole, cariprazine, iloperidone, lumateperone and pimavanserin
- medicines used to treat asthma and other lung-related problems such as chronic obstructive pulmonary disease (COPD), such as salmeterol and theophylline
- medicines used to treat high blood pressure (hypertension), such as amlodipine, diltiazem, nifedipine, verapamil and aliskiren
- medicines used to prevent blood clots, such as ticagrelor, vorapaxar, clopidogrel and cilostazol
- corticosteroids used to treat inflammation, such as betamethasone, budesonide, ciclesonide, dexamethasone, fluticasone, methylprednisolone, mometasone, prednisolone and triamcinolone
- medicines used to treat cystic fibrosis, such as ivacaftor, elexacaftor/tezacaftor/ivacaftor, tezacaftor/ivacaftor
- medicines used to treat diabetes, such as saxagliptin
- medicines used to treat hepatitis C virus infection, such as glecaprevir/pibrentasvir
- medicines used to lower blood cholesterol, such as atorvastatin, fluvastatin, pravastatin and rosuvastatin
- medicines used to suppress your immune system, such as cyclosporine, tacrolimus, everolimus and sirolimus
- medicines used to treat inflammatory arthritis, such as tofacitinib and upadacitinib
- medicines used to treat migraine headaches, such as rimegepant
- medicines to treat overactive bladder, such as darifenacin

- medicines used to treat erectile dysfunction (also known as impotence), such as sildenafil and tadalafil
- medicines used to treat high blood pressure in the blood vessels that supply the lungs, such as tadalafil (Adcirca®), bosentan and riociguat
- medicines used as sedatives, hypnotics and sleeping agent, such as alprazolam, buspirone, clonazepam, clorazepate, diazepam, estazolam, flurazepam and zolpidem
- any of the following other specific medicines:
 - bupropion (used for smoking cessation)
 - oral or patch contraceptive containing ethinylestradiol used to prevent pregnancy: barrier or non-hormonal methods of contraception should be considered during the 5 days of Paxlovid treatment and until one menstrual cycle after stopping Paxlovid
 - midazolam administered by injection (used for sedation [an awake but very relaxed state of calm or drowsiness during a medical test or procedure] or anaesthesia)
 - levothyroxine (used to treat an underactive thyroid gland [hypothyroidism])

Many medicines interact with Paxlovid. **Keep a list of your medicines to show your doctor and pharmacist.** Do not start taking a new medicine without telling your doctor. Your doctor can tell you if it is safe to take Paxlovid with other medicines.

Pregnancy, breast-feeding and fertility

There is not enough information to be sure that Paxlovid is safe for use in pregnancy and it is not known if Paxlovid will harm your baby while you are pregnant. If you are pregnant, it is not recommended to use Paxlovid unless your clinical condition requires this treatment.

If you are pregnant, think you may be pregnant, or are planning to have a baby, ask your doctor for advice. If you can become pregnant, it is recommended that you refrain from sexual activity or use effective barrier contraception while taking Paxlovid and until after one full menstrual cycle is completed after stopping Paxlovid treatment.

If you are breast-feeding or are planning to breastfeed, tell your healthcare provider before taking this medicine. Breast-feeding is not recommended during treatment and for 7 days after the last dose of Paxlovid. This is because it is not known if Paxlovid gets into breast milk and will be passed to the baby.

Driving and using machines

Paxlovid has not been specifically tested for its possible effects on the ability to drive a car or operate machines.

Paxlovid contains lactose (a type of sugar)

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Information on sodium content

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to take Paxlovid

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

If you have kidney disease, please talk to your healthcare provider for an appropriate dose of Paxlovid. If you have moderate kidney disease you will need a lower dose of Paxlovid. If you have severe kidney disease you must not take Paxlovid.

Paxlovid consists of 2 medicines: nirmatrelvir and ritonavir. The recommended dose is 2 tablets of nirmatrelvir with 1 tablet of ritonavir by mouth twice daily (in the morning and at night). The blister foil for each day of treatment is divided in two different coloured sections to indicate which tablets need to be taken at each time of day – one side for the morning (AM) dose and the other side for the evening (PM) dose.

A course of treatment lasts 5 days. For each dose, take all 3 tablets together at the same time.

Swallow the tablets whole. Do not chew, break or crush the tablets. Paxlovid can be taken with or without meals.

Use in children and adolescents

Paxlovid is not used to treat children (under 12 years old).

If you take more Paxlovid than you should

If you take too much Paxlovid, call your healthcare provider or go to the nearest hospital emergency room right away.

If you forget to take Paxlovid

If you forget to take a dose of Paxlovid, take it as soon as you remember. If more than 8 hours have passed since your missed dose, then do not take the missed dose and just carry on as before.

Do not take a double dose to make up for a forgotten dose.

If you feel better

Even if you feel better, do not stop taking Paxlovid without talking to your healthcare provider.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Not many people have taken Paxlovid. Serious and unexpected side effects may happen.

Common: may affect up to 1 in 10 people

- Diarrhoea
- Nausea
- Altered sense of taste (such as metallic, bitter taste)
- Headache

Uncommon: may affect up to 1 in 100 people

- Allergic reaction (such as hives, trouble swallowing or breathing, swelling of the mouth, lips, or face, throat tightness, hoarseness or skin rash)
- Vomiting
- Abdominal pain
- High blood pressure

Rare: may affect up to 1 in 1,000 people

- Severe allergic reaction known as ‘anaphylaxis’ (such as swelling of tongue, mouth and face, trouble swallowing or breathing, throat tightness, or hoarseness)
- Serious skin reactions known as ‘toxic epidermal necrolysis’ and ‘Stevens-Johnson syndrome’ (such as red and painful skin, blisters and peeling skin, blisters or sores in your mouth or lips)
- Feeling generally unwell

Reporting of side effects

If you get any adverse events, talk to your doctor or pharmacist. This includes any possible adverse events not listed in this leaflet. You can also report adverse events directly via online reporting through the FDA Philippines website at <https://www.fda.gov.ph/pharmacovigilance/> and include batch/lot number if available. By reporting adverse events, you can help provide more information on the safety of this medicine.

In addition, you can report adverse events to Pfizer, Inc. at the contact information provided below.

<i>Alternate reporting via email and fax</i>	<i>Contact numbers</i>
<i>Email:</i> PHL.AEReporting@pfizer.com	+63 917 8108146
<i>Fax:</i> 1 800 1110 1520 (Toll Free)	+63 2 8451 9288 +63 2 8415 9200 ext 19288

5. How to store Paxlovid

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton or the blister after 'EXP'. The expiry date refers to the last day of that month.

Store below 25°C.

Do not refrigerate or freeze.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Paxlovid contains

- The active substances in this medicine are nirmatrelvir and ritonavir.
 - Each pink film-coated nirmatrelvir tablet contains 150 mg of nirmatrelvir.
 - Each white film-coated ritonavir tablet contains 100 mg of ritonavir.
- The other ingredients in nirmatrelvir are microcrystalline cellulose, lactose monohydrate (see section 2, 'Paxlovid contains lactose'), croscarmellose sodium, colloidal silicon dioxide and sodium stearyl fumarate. The film-coating contains hypromellose, titanium dioxide, macrogol and iron oxide red.
- The other ingredients in ritonavir are copovidone, sorbitan laurate, silica colloidal anhydrous, calcium hydrogen phosphate anhydrous and sodium stearyl fumarate. The film-coating contains hypromellose, titanium dioxide, macrogol, hydroxypropyl cellulose, talc, silica colloidal anhydrous and polysorbate 80.

What Paxlovid looks like and contents of the pack

Paxlovid tablets are available in 5 daily-dose blister cards with a total of 30 tablets packaged in a carton.

Each daily blister card contains 4 nirmatrelvir tablets (150 mg each) and 2 ritonavir tablets (100 mg each) and indicates which tablets need to be taken in the morning and evening.

Nirmatrelvir 150 mg film-coated tablets are pink, oval-shaped and debossed with 'PFE' on one side and '3CL' on the other side.

Ritonavir 100 mg film-coated tablets are white to off white, capsule shaped and debossed with 'H' on one side and 'R9' on the other side.

For any information about this medicine, please contact the Emergency Use Authorization (EUA) Holder:

Pfizer, Inc.

19F – 20F, 8 Rockwell Bldg., Hidalgo Drive
Rockwell Center, Poblacion, Makati City 1210
Metro Manila, Philippines

Fax number: 1 800 1110 1520 (Toll Free)

Contact numbers: +63 9175171575, +63 2 8451 9288, +63 2 8415 9200 ext 19288

Please submit your medical information inquiries to <https://pmiform.com/CONS/PH> or for healthcare professionals please visit www.pfizermedicalinformation.ph.

Scan the code with a mobile device to get the latest version of the label.



URL: www.covid19oralrx.com

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