PAXLOVID FILM COATED TABLET

Nirmatrelvir 150 mg and Ritonavir 100 mg

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What Paxlovid is used for

Paxlovid is an antiviral medicine used for treating mild-to-moderate COVID-19.

COVID-19 is caused by a virus. Paxlovid is used in adults 18 years of age and older who do not require supplemental oxygen and who are at increased risk for progression to severe COVID-19, including hospitalization or death.

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

How Paxlovid works

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.

This medicine contains the active substances nirmatrelvir and ritonavir in two different tablets. Nirmatrelvir is active against the virus that causes COVID-19. Ritonavir prolongs the therapeutic effect of nirmatrelvir.

Before you use Paxlovid

- *When you must not use it*

- if you are allergic to nirmatrelvir, ritonavir or any of the other ingredients of this medicine.
- if you have severe liver 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, enzalutamide (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)
  - eletriptan, ubrogepant (used to treat migraine headaches)
  - dihydroergotamine, ergonovine, ergotamine, 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, primidone, phenytoin (used to prevent and control seizures)
  - rifampicin, rifapentine (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)

Do not give this medicine to children and adolescents under 18 years because this medicine has not been studied in children and adolescents.

- *Before you start to use it*

Tell your doctor if you have or have had a liver or kidney disease. If you have moderate kidney disease you will need a lower dose of Paxlovid. Do not take Paxlovid if you have severe liver or kidney

disease.

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

There is not enough information to be sure that Paxlovid is safe for use in pregnancy, and it is not known if this medicine will harm your baby while you are pregnant. If you are pregnant, it is not recommended to use this medicine 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 before taking this medicine. If you can become pregnant, it is recommended that you refrain from sexual activity or use effective barrier contraception while taking this medicine and until after one full menstrual cycle is completed after stopping the treatment. **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.

If you are breast-feeding or are planning to breastfeed, tell your healthcare provider before taking this medicine. A small amount of Paxlovid passes into breast milk. You should not breast-feed your baby while taking this medicine and for 48 hours after completing the treatment as a precaution.

Allergic reactions
Severe allergic reactions (known as 'anaphylaxis'), including serious skin reactions (known as 'toxic epidermal necrolysis' and 'Stevens Johnson syndrome') can happen in people taking this medicine, even after only 1 dose. Stop taking this medicine 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
Paxlovid treatment may result in medicines used to treat HIV becoming less effective.

- *Taking other medicines*

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

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

- Above mentioned medicines that may cause serious or life-threatening side effects or affect how Paxlovid works (refer to section *When you must not use it)*
- 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 and correct irregular heartbeats, such as digoxin and disopyramide
- 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, cancer such as afatinib, abemaciclib, apalutamide, ceritinib, dasatinib, nilotinib, vincristine, vinblastine, encorafenib, fostamatinib, ibrutinib, ivosidenib
- medicines used to thin the blood (anticoagulants) such as warfarin, rivaroxaban, vorapaxar, apixaban and dabigatran
- medicines used to treat convulsions such as divalproex and lamotrigine
- medicines used to treat depression, such as amitriptyline, fluoxetine, imipramine, nortriptyline, paroxetine, sertraline and desipramine, trazodone
- medicines used to treat fungal infections (antifungals), such as itraconazole, ketoconazole and voriconazole
- medicines used to treat allergies, such as fexofenadine and loratadine
- medicines used to treat HIV infection, such as atazanavir, darunavir, efavirenz, maraviroc and zidovudine
- medicines used to treat bacterial infections (antibiotics and antimycobacterials), such as atovaquone, clarithromycin, delamanid, erythromycin, sulfamethoxazole/trimethoprim, bedaquiline, rifabutin, and rifapentine

- medicines used to treat infections by parasites (antiparasitics), such as albendazole
- medicines used to treat mental or mood disorders, such as clozapine, haloperidol, risperidone and thioridazine
- medicines used to treat high blood pressure (hypertension), such as amlodipine, diltiazem, nifedipine, verapamil and aliskiren
- medicines used to treat heart and/or blood vessel problems, such as ticagrelor, vorapaxar, clopidogrel, cilostazol, and mavacamten.
- 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/ivacaft or tezacaftor/ivacaftor
- medicines used to treat diabetes, such as saxagliptin
- antiviral medicine used to treat hepatitis C virus infection, such as glecaprevir/pibrentasvir
- oral or a 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.
- medicines used to lower blood cholesterol, such as atorvastatin, fluvastatin, pravastatin and rosuvastatin
- medicines used to suppress your immune system, such as cyclosporine, tacrolimus and 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 mental disorders, such as suvorexant, aripiprazole, brexpiprazole, cariprazine, iloperidone, lumateperone and pimavanserin
- 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
- medicines used for smoking cessation, such as bupropion
- 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])

How to use Paxlovid

- *How much to use*

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

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 in the evening). 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.
For each dose, take all 3 tablets together at the same time.

- *When to use it*

Use as directed by your doctor or pharmacist.

Paxlovid can be taken with or without food.

Swallow the tablets whole. Do not chew, break or crush the tablets.

- *How long to use it*

A course of treatment lasts 5 days.

It is important to take Paxlovid as prescribed unless your doctor tells you to stop your treatment.

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

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

- *If you forget to use it*

Consult your doctor or pharmacist on what you should do if you forget to use it.

If you forget to take a dose of this medicine, take it as soon as you remember. If more than 8 hours

have passed since your missed dose, do not take the missed dose and wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- *If you use too much (overdose)*

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. If you have taken too much of your medicine, it is recommended that you should be monitored for signs and symptoms of any side effects.

While you are using it

- *Things you must do*

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Paxlovid.

Tell your doctor immediately if you become pregnant while taking this medication.

- *Things you must not do*

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give Paxlovid to anyone else, even if they have the same symptoms or condition as you.

- *Things to be careful of*

Driving or using machines

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

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. Paxlovid is still being studied, so it is possible that all of the risks are not known at this time.

***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)
- Abdominal pain
- Vomiting
- 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

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers →Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Paxlovid

- *Storage*

Keep this medicine out of the reach and sight of children.
Store below 25°C.
Do not refrigerate or freeze.

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.

- *Disposal*

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- *What it looks like*

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

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.

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.

*Not all pack sizes may be marketed.

- *Ingredients*

- Active ingredient:
  The active substance of Paxlovid film-coated tablets are nirmatrelvir and ritonavir.
  - Each pink film-coated nirmatrelvir tablet contains 150 mg nirmatrelvir.
  - Each white film-coated ritonavir tablet contains 100 mg ritonavir.

- Inactive ingredients:
  Nirmatrelvir

  Tablet core:
  - Microcrystalline cellulose
  - Lactose monohydrate
  - Croscarmellose sodium
  - Colloidal silicon dioxide
  - Sodium stearyl fumarate

  Film-coat:
  - Hypromellose (E464)
  - Titanium dioxide (E171)
  - Macrogol (E1521)
  - Iron oxide red (E172)

  Ritonavir

  Tablet core:
  - Copovidone
  - Sorbitan laurate
  - Silica colloidal anhydrous (E551)
  - Calcium hydrogen phosphate anhydrous
  - Sodium stearyl fumarate

  Film-coat:
  - Hypromellose (E464)
  - Titanium dioxide (E171)
  - Macrogol (E1521)
  - Hydroxypropyl cellulose (E463)
  - Talc (E553b)
  - Silica, colloidal anhydrous (E551)
  - Polysorbate 80 (E433)

- *MAL numbers*

  Paxlovid (nirmatrelvir 150 mg film-coated tablets and ritonavir 100 mg film-coated tablets)
  MAL22036001ACRZ (Pfizer Manufacturing Deutschland GmbH)
  MAL22036002ACRSZ (Pfizer Ireland Pharmaceuticals)

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