

PAXLOVID FILM COATED TABLET

PF-07321332 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 with mild-to-moderate COVID-19. It is only used in patients who are at high 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.

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.

Before you use Paxlovid

- When you must not use it

- if you are allergic to PF-07321332, ritonavir or any of the other ingredients of this medicine
- 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)

- pethidine, piroxicam, propoxyphene (used to relieve pain)
- ranolazine (used to treat chronic chest pain [angina])
- dronedarone (used to correct irregular heartbeats)
- colchicine (used to treat gout)
- lurasidone (used to treat depression)
- pimozide and clozapine (used to treat abnormal thoughts or feelings)
- dihydroergotamine and ergotamine (used to treat migraine headaches)
- methylergonovine (used to stop excessive bleeding that may occur following childbirth or an abortion)
- cisapride (used to relieve certain stomach problems)
- lovastatin, simvastatin (used to lower blood cholesterol)
- 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)
- rifampin (used to treat tuberculosis)
- St. John's Wort (*Hypericum perforatum*) (a herbal remedy used for depression and anxiety)

Do not give Paxlovid to children and adolescents under 18 years because Paxlovid 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 been told by your

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

Paxlovid is not recommended during pregnancy. 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, 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.

- Taking other medicines

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

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

- anticancer medicines (e.g., afatinib, abemaciclib, apalutamide, ceritinib, dasatinib, encorafenib, fostamatinib, ibrotinib, ivosidenib, neratinib, nilotinib, venetoclax, vinblastine, vincristine)
- anticoagulants (e.g.,

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- warfarin, rivaroxaban, vorapaxar, apixaban and dabigatran)
- medicines used to treat convulsions (e.g., divalproex, lamotrigine and phenytoin)
- medicines used for smoking cessation (e.g., bupropion)
- anti-allergic medicines (e.g., fexofenadine and loratadine)
- antifungals (e.g., ketoconazole, itraconazole, voriconazole)
- medicines to treat HIV infection (e.g., amprenavir, atazanavir, darunavir, fosamprenavir, efavirenz, maraviroc, nevirapine, raltegravir, zidovudine)
- medicines used to treat bacterial infections (antibiotics and antimycobacterials), such as tovaquone, clarithromycin, erythromycin, bedaquiline, rifabutin, delamanid and sulfamethoxazole/trimethoprim)
- quetiapine (used to treat schizophrenia, bipolar disorder and major depressive disorder)
- medicines used to treat mental or mood disorders, such as haloperidol, risperidone and thioridazine
- medicines used to treat high blood pressure in the blood vessels that supply the lungs, such as bosentan and riociguat
- medicines used to treat high blood pressure (hypertension) (e.g., amlodipine, diltiazem, nifedipine)
- medicines used to treat heart conditions and correct irregular heartbeats, such as digoxin
- medicines used to correct irregular heartbeats (e.g., amiodarone, bepridil,

- quinidine)
- antiviral medicine used to treat hepatitis C virus infection (e.g., glecaprevir/pibrentasvir)
- medicines used to lower blood cholesterol (e.g., atorvastatin, fluvastatin, pravastatin and rosuvastatin)
- hormonal contraceptives including ethinylestradiol (oral or a patch contraceptive to prevent pregnancy).
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
- medicines used to suppress your immune system, such as (e.g., cyclosporine, tacrolimus, everolimus)
- salmeterol and theophylline (used to treat asthma and other lung-related problems such as chronic obstructive pulmonary disease [COPD])
- medicines used to treat severe pain, such as morphine and morphine-like medicines used to treat severe pain (e.g., fentanyl, methadone, buprenorphine, norbuprenorphine)
- medicines used as sedatives, hypnotics and sleeping agent, such as alprazolam, buspirone and zolpidem
- midazolam administered by injection (sedative)
- steroids (e.g., beta methasone, budesonide, ciclesonide, dexamethasone, fluticasone, prednisolone methylprednisolone, mometasone, prednisone, triamcinolone)
- 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 depressions, such as amitriptyline, fluoxetine, imipramine, nortriptyline, paroxetine, sertraline and desipramine
- medicines used to treat erectile dysfunction (also known as impotence), such as sildenafil and tadalafil
- levothyroxine (used to treat an underactive thyroid gland [hypothyroidism])

Paxlovid treatment may result in medicines used to treat HIV becoming less effective.

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: PF-07321332 and ritonavir. The recommended dose is 2 tablets of PF-07321332 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.

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

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- 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 Paxlovid 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.

Take the missed dose as soon as you remember. If it is almost time for your next dose, 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 side-effects

- Diarrhoea
- Vomiting
- Altered sense of taste

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

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 PF-07321332 tablets (150 mg each) and 2 ritonavir tablets (100 mg each) and indicates which tablets need to be taken in the morning and evening.

PF-07321332 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.

*Not all pack sizes may be marketed.

- Ingredients

- Active ingredient:

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The active substance of Paxlovid film-coated tablets are PF-07321332 and ritonavir.

- Each pink film-coated PF-07321332 tablet contains 150 mg PF-07321332.
- Each white film-coated ritonavir tablet contains 100 mg ritonavir.

- **Inactive ingredients:**

- PF-07321332
- 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 (PF-07321332 150 mg film-coated tablets and ritonavir 100 mg film-coated tablets)
MAL*****

Manufacturer

PF-07321332:

Pfizer Manufacturing Deutschland GmbH
Betriebsstätte Freiburg
Mooswaldallee 1
79090 Freiburg, Germany

Pfizer Ireland Pharmaceuticals
Little Connell
Newbridge,
Ireland (IRL)

Ritonavir:

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22-110,
Industrial Development Area,
Jeedimetla,
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Product Registration Holder

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59200 Kuala Lumpur, Malaysia

Date of Revision

18/02/2022

Serial Number

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