

Package leaflet: Information for the patient

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

▼ 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. See the end of section 4 for how to report side effects.

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
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1. What Paxlovid is and what it is used for

Paxlovid contains two active substances nirmatrelvir and ritonavir in two different tablets. Paxlovid is an antiviral medicine used for treating adults with COVID-19 who do not require supplemental oxygen and who are at increased risk for progressing to severe disease.

COVID-19 is caused by a virus called a coronavirus. This medicine 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 prevent you from developing severe illness.

You must talk to a doctor if you do not feel better or if you feel worse after 5 days.

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 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])
 - Dronedarone, propafenone, quinidine (used to treat heart conditions and correct irregular heartbeats)
 - Rifampicin, rifapentine (used to treat bacterial infections)
 - Apalutamide, enzalutamide, neratinib, venetoclax (used to treat cancer)
 - Carbamazepine, phenobarbital, phenytoin, primidone (used to prevent and control seizures)
 - Colchicine (used to treat gout)

- Terfenadine (used to treat allergies)
- Cariprazine and lurasidone (used to treat schizophrenia)
- Pimozide, quetiapine (used to treat schizophrenia, bipolar disorder, severe depression and abnormal thoughts or feelings)
- Silodosin (used to treat enlarged prostate gland)
- Eplerenone and ivabradine (used to treat heart and/or blood vessel problems)
- Dihydroergotamine and ergotamine (used to treat migraine headaches)
- Ergonovine and methylergonovine (used to stop excessive bleeding that may occur following childbirth or an abortion)
- Cisapride (used to relieve certain stomach problems)
- St. John's wort (*Hypericum perforatum*) (a herbal remedy used for depression and anxiety)
- Voclosporin (used to treat immune disorders)
- Lovastatin, simvastatin, lomitapide (used to lower blood cholesterol)
- Eletriptan (used to treat migraine headaches)
- Lumacaftor/ivacaftor (used for cystic fibrosis)
- Finerenone (used to treat chronic kidney disease associated with Type 2 diabetes)
- Naloxegol (used to treat opioid-induced constipation)
- Avanafil, vardenafil (used to treat erectile dysfunction [also known as impotence])
- Sildenafil, tadalafil (used to treat erectile dysfunction [also known as impotence] or pulmonary arterial hypertension [high blood pressure in the pulmonary artery])
- Clorazepate, diazepam, estazolam, flurazepam, triazolam, midazolam taken orally (used to relieve anxiety and/or trouble sleeping)
- Tolvaptan used to treat hyponatremia (low sodium levels in the blood)

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 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
- itching
- skin rash
- red and painful skin
- blisters and peeling skin
- blisters or sores in your mouth or lips

Liver disease

Tell your doctor if you have or have had a liver disease. Liver enzyme abnormalities, hepatitis and jaundice have occurred in patients receiving ritonavir.

Kidney disease

Tell your doctor if you have or have had a kidney disease.

High blood pressure

Tell your doctor if you have high blood pressure. Your doctor may need to check your blood pressure before taking this medicine and while you are taking this medicine. There have been reports of high blood pressure in people taking this medicine, particularly in older individuals.

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.

Children and adolescents

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

Other medicines and Paxlovid

There are other medicines that may not be taken together with Paxlovid. Tell your doctor(s) or pharmacist if you are taking, have recently taken or might take any other medicines:

- medicines used to treat cancer, such as afatinib, abemaciclib, ceritinib, dasatinib, encorafenib, fostamatinib, ibrutinib, ivosidenib, nilotinib, vinblastine and vincristine
- medicines used to thin the blood (anticoagulants), such as warfarin, rivaroxaban, dabigatran and apixaban
- medicines used to treat convulsions, such as divalproex, lamotrigine and clonazepam
- medicines used for smoking cessation, such as bupropion
- medicines used to treat allergies, such as fexofenadine and loratadine
- medicines used to treat fungal infections (antifungals), such as itraconazole and voriconazole
- medicines used to treat Cushing's syndrome—when the body produces an excess of cortisol—such as ketoconazole tablets
- medicines used to treat HIV infection, such as efavirenz, maraviroc, raltegravir, zidovudine and bictegravir/emtricitabine/tenofovir
- medicines used to treat infections (e.g., antibiotics and antimycobacterials), such as atovaquone, clarithromycin, erythromycin, fusidic acid (taken orally or administered by IV route), bedaquiline, rifabutin, delamanid and sulfamethoxazole/trimethoprim
- medicines used to treat schizophrenia and abnormal thoughts or feelings, such as clozapine
- 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), such as amlodipine, diltiazem, felodipine, lercanidipine, nicardipine, nifedipine and verapamil
- medicines used to treat heart and/or blood vessel problems, such as aliskiren, ticagrelor, cilostazol and clopidogrel
- medicines used to treat heart conditions and correct irregular heartbeats, such as digoxin, amiodarone, flecainide and disopyramide
- medicines to treat cystic fibrosis, such as ivacaftor, elexacaftor/tezacaftor/ivacaftor and tezacaftor/ivacaftor
- medicines used to treat diabetes such as saxagliptin
- medicines used to treat hepatitis C virus infection, such as glecaprevir/pibrentasvir and sofosbuvir/velpatasvir/voxilaprevir
- medicines used to lower blood cholesterol, such as atorvastatin, fluvastatin, pravastatin and rosuvastatin
- medicines used to treat migraine headaches, such as rimegepant
- medicines used to treat urinary incontinence, such as darifenacin and solifenacin
- medicines used to treat mental health problems, such as aripiprazole and brexpiprazole
- medicines used to suppress your immune system, such as cyclosporine, everolimus, sirolimus and tacrolimus
- medicines used to treat autoimmune disorders including rheumatoid arthritis, psoriatic arthritis or ulcerative colitis, such as tofacitinib and upadacitinib
- medicines used to treat severe pain, such as morphine, fentanyl, oxycodone, methadone, buprenorphine, other morphine-like medicines, pethidine and piroxicam
- medicines used as sedatives, hypnotics, and sleeping agent, such as alprazolam, buspirone and zolpidem

- medicines used to treat attention deficit disorder or a sleep disorder called narcolepsy, such as amphetamines
- steroids including corticosteroids used to treat inflammation, such as budesonide, dexamethasone, fluticasone, prednisolone and 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 depression, such as amitriptyline, fluoxetine, imipramine, nortriptyline, paroxetine and sertraline
- medicines used as thyroid replacement therapy, such as levothyroxine
- medicine used to treat enlarged prostate, such as tamsulosin
- any of the following other specific medicines:
 - oral or patch contraceptive containing ethinyl estradiol used to prevent pregnancy
 - 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)

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

Pregnancy and breast-feeding

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.

There is not enough information to be sure that Paxlovid is safe for use in pregnancy. If you are pregnant, it is not recommended to use this medicine unless your clinical condition requires this treatment. It is recommended that you refrain from sexual activity or use contraception while taking this medicine and for 7 days after completing the treatment as a precaution. If you are taking hormonal contraception, as this medicine may reduce the effectiveness of this medicine, it is recommended that a condom or other non hormonal method of contraception is used. Your doctor will advise you on the duration of this required adjustment of your contraceptive measures.

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.

Driving and using machines

Paxlovid is expected to have no influence on the ability to drive and use machines.

Paxlovid contains lactose

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

Paxlovid contains sodium

Nirmatrelvir and ritonavir tablets each contain 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.

Paxlovid consists of 2 medicines: nirmatrelvir and ritonavir.

A course of treatment lasts 5 days.

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

Recommended dose

No kidney disease or mild kidney disease

If you have NO kidney disease or MILD kidney disease, the recommended dose is **2** pink nirmatrelvir tablets with **1** white ritonavir tablet by mouth twice daily (in the morning and in the evening).

Moderate kidney disease

If you have MODERATE kidney disease, the recommended dose is **1** pink nirmatrelvir tablet with **1** white ritonavir tablet by mouth twice daily (in the morning and in the evening).

Severe kidney disease

If you have SEVERE kidney disease, the recommended dose is **2** pink nirmatrelvir tablets with **1** white ritonavir tablet by mouth once **on Day 1**, and then **1** pink nirmatrelvir tablet with **1** white ritonavir tablet once daily **on Days 2 to 5**.

If you take more Paxlovid than you should

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

If you forget to take Paxlovid

If you miss a dose of this medicine 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 at the same time.

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

If you stop taking Paxlovid

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

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.

Common: may affect up to 1 in 10 people

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

Uncommon: may affect up to 1 in 100 people

- Allergic reactions
- High blood pressure
- Abdominal pain
- Muscle pain
- Skin rash (also reported as part of allergic reaction)

Rare: may affect up to 1 in 1000 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)
- Malaise

- Itching (also reported as part of allergic reaction)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland

HPRA Pharmacovigilance. Website: www.hpra.ie.

Malta

ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal

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.

This medicine does not require any special storage conditions.

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 the nirmatrelvir tablet are microcrystalline cellulose, lactose monohydrate (see section 2, 'Paxlovid contains lactose'), croscarmellose sodium, colloidal silicon dioxide and sodium stearyl fumarate (see section 2, 'Paxlovid contains sodium'). The film-coating contains hydroxypropyl methylcellulose, titanium dioxide, macrogol/polyethylene glycol and iron oxide red.
- The other ingredients in the ritonavir tablet are copovidone, sorbitan laurate, colloidal anhydrous silica, calcium hydrogen phosphate, sodium stearyl fumarate. The film-coating contains hypromellose, titanium dioxide, macrogol/polyethylene glycol, hydroxypropyl cellulose, talc, colloidal anhydrous silica and polysorbate 80.

What Paxlovid looks like and contents of the pack

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.

Twice daily dose blister card

Paxlovid film-coated 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 (sun and moon symbols).

Once daily dose blister card

Paxlovid film-coated tablets are available in a 5-day blister card with a total of 11 tablets packaged in a carton.

The 5-day blister card contains 6 nirmatrelvir tablets (150 mg each) and 5 ritonavir tablets (100 mg each) and indicates which tablets need to be taken once daily for 5 days.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Pfizer Europe MA EEIG
Boulevard de la Plaine 17
1050 Brussels
Belgium

Manufacturer

Pfizer Manufacturing Deutschland GmbH
Mooswaldallee 1
79108 Freiburg Im Breisgau
Germany

Pfizer Italia S.r.L.
Localita Marino del Tronto
63100 Ascoli, Piceno
Italy

Pfizer Ireland Pharmaceuticals Unlimited Company
Little Connell
Newbridge
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Ireland

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Ireland

Pfizer Healthcare Ireland Unlimited Company
Tel: 1800 633 363 (toll free)
+44 (0)1304 616161

Malta

Vivian Corporation Ltd.
Tel: + 356 21344610

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Scan the code with a mobile device to get the package leaflet in different languages.



URL: www.covid19oralrx.com

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:
<https://www.ema.europa.eu>.

This leaflet is available in all EU/EEA languages on the European Medicines Agency website.

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