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 give it 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 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 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.

### 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)
  - pethidine, propoxyphene (used to relieve pain)
  - ranolazine (used to treat chronic chest pain [angina])
  - nortriptyline, venetoclax (used to treat cancer)
  - amiodarone, bepridil, dronedarone, enacindine, 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 (used to treat depression)
  - pimozide, clozapine, quetiapine (used to treat schizophrenia, bipolar disorder, severe depression and abnormal thoughts or feelings)
  - dihydroergotamine and ergotamine (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)
  - lovastatin, simvastatin, lovastatin (used to lower blood cholesterol)
  - 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)
  - clonazepam, diazepam, estazolam, flurazepam, triazolam, midazolam taken orally (used to relieve anxiety and/or trouble sleeping)
  - carbamazepine, phenobarbital, phenytoin (used to prevent and control seizures)
  - rifampin (used to treat tuberculosis)
  - St. John’s Wort (Hypericum perforatum) (a herbal remedy used for depression and anxiety)
  - norbuprenorphine and other morphine-like medicines
  - fentanyl, methadone, buprenorphine, norbuprenorphine and other morphine-like medicines
  - medications used to treat cancer, such as afatinib, abemaciclib, apalutamide, ceritinib, dasatinib, nilotinib, vincristine, vinblastine, encorafenib, fostamatinib, irinotecan and oxasendin
  - medicines used to treat attention disorders, such as methylphenidate and amphetamines
  - medicines used to treat severe pain, such as morphine, fentanyl, methadone, buprenorphine, naltrexone, oxycodone, oxycodeone and ephedrine
  - medications used to treat heart conditions and correct irregular heartbeats, such as digoxin
  - medicines used to treat severe pain, such as morphine, fentanyl, methadone, buprenorphine, naltrexone, oxycodone, oxycodeone and ephedrine
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**Warnings and precautions**

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

**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 and adolescents under 18 years because Paxlovid has not been studied in children and adolescents.

**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:

- medications used to treat attention disorders, such as amphetamines (e.g. methylphenidate and dexamphetamine)
- medicines used to treat severe pain, such as morphine, fentanyl, methadone, buprenorphine, naltrexone, oxycodone, oxycodeone and ephedrine
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- medications used to treat heart conditions and correct irregular heartbeats, such as digoxin
- medicines used to treat cancer, such as afatinib, abemaciclib, apalutamide, ceritinib, dasatinib, nilotinib, vincristine, vinblastine, encorafenib, fostamatinib, irinotecan and oxasendin
- other medicines that may not mix with Paxlovid
• medicines used to thin the blood (anticoagulants), such as warfarin, apixaban, dabigatran, rivaroxaban and vorapaxar
• medicines used to treat convulsions, such as divalproex, lamotrigine and phenytoin
• medicines used to treat depressions, such as amitriptyline, fluoxetine, imipramine, nortriptyline, paroxetine, sertraline and desipramine
• medicines used to treat allergies, such as desloratadine and loratadine
• medicines used to treat fungal infections (antifungals), such as ketoconazole, itraconazole and voriconazole
• medicines used to treat bacterial infections (antibiotics and antimalarials), such as rifabutin, erythromycin, atovaquone, bedaquiline, delamanid, clarithromycin and sulfamethoxazole/trimethoprim
• medicines used to treat HIV infection, such as amprinavir, atazanavir, darunavir, fosamprenavir, elafavir, maraviroc, raltegravir and voriconazole
• medicines used to treat mental or mood disorders, such as haloperidol, risperidone and thioridazine
• 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 amlopidine, diltiazem and nifedipine
• medicines used to treat high blood pressure in the blood vessels that supply the lungs, such as bosentan and trocacyl
• medicines used to treat hepatitis C virus infection, such as glecaprevir/pibrentasvir
• medicines used to lower blood cholesterol, such as simvastatin, pravastatin and rosvastatin
• medicines used to suppress your immune system, such as cyclosporine, tacrolimus and everolimus
• medicines used to treat erectile dysfunction (also known as impotence), such as sildenafil and tadalafil
• medicines used as sedatives, hypnotics and sleeping aids, such as zopiclone, zolpidem and zaleplon
• medicines used sedatives, hypnotics and sleeping aids, such as alprazolam, buspirone and zopiclom
• atorvastatin containing corticosteroids used to treat inflammation, such as budesonide, dexamethasone, fluticasone propionate, prednisolone and triamcinolone
• any of the following other specific medicines:
  • bupropion (used for smoking cessation)
  • oral or patch contraceptive containing ethinylestradiol used to prevent pregnancy
  • midazolam administered by injection used for sedation [an awake but very relaxed state of calm or drowsiness (hypothyroidism)]
  • levothyroxine (used to treat an underactive thyroid gland)
  • midazolam administered by injection used for sedation [an awake but very relaxed state of calm or drowsiness (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
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.

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 into 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 and adolescents (under 18 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. Paxlovid is still being studied, so it is possible that all of the risks are not known at this time.

Common:
• Diarrhoea
• Vomiting
• Alteration of taste

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 via the Coronavirus Yellow Card Reporting site at https://coronavirus-yellowcard.mhra.gov.uk or search for Mhra Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

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 film-coated ritonavir tablet contains 100 mg of ritonavir.

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– 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 hydroxypropyl cellulose, titanium dioxide, macrogol and iron oxide red.

– The other ingredients in ritonavir are croscarmellose sodium, colloidal silicon dioxide and sodium stearyl fumarate. The film-coating contains hydroxypropyl cellulose, titanium dioxide, macrogol and iron oxide red.

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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 ritonavir tablets (150 mg each) and 2 nirmatrelvir 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 ‘PF’ 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.

Marketing Authorisation Holder
Pfizer Limited
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom

Manufacturer
Pfizer Manufacturing Deutschland GmbH
Betriebstätte Freiburg
Mooswaldtaler 11
79090 Freiburg
Germany
For any information about this medicine, please contact:
Medical Information, Pfizer UK Ltd, Walton Oaks, Docking Road, Tadworth, Surrey, KT20 7NS.
Telephone 01304 616161.

This leaflet was last revised in 02/2022.
This medicine has been given ‘conditional approval’. This means that there is more evidence to come about this medicine.

The Agency will review new information on this medicine at least every year and this leaflet will be updated as necessary.
Ref: PX 4_0
What you need to know before you take Paxlovid

What Paxlovid is and what it is used for

Paxlovid is a medicine that contains nirmatrelvir and ritonavir. It is used to treat COVID-19 in adults and adolescents who are at high risk for progression to severe COVID-19.

What you need to know before you take Paxlovid

1. If you have severe liver or kidney disease, Paxlovid may not be the right treatment for you. Your doctor or pharmacist will advise you if you have these conditions.

2. If you are at high risk for severe COVID-19 and you need to take Paxlovid, your doctor may use a lower dose of Paxlovid.

3. Paxlovid will allow quick identification of new safety information.

4. In particular, you should inform your doctor or pharmacist if you have severe liver or kidney disease, or if you are at high risk for progression to severe COVID-19.

5. Paxlovid is a medicine that contains nirmatrelvir and ritonavir. It is used to treat COVID-19 in adults and adolescents who are at high risk for progression to severe COVID-19.

What you need to know after you take Paxlovid

What to do if you forget to take Paxlovid

If you forget to take a dose of Paxlovid, take it as soon as possible, but as soon as you remember. If more than 12 hours have passed since you were supposed to take Paxlovid, do not take the missed dose. Instead, just carry on as before.

What to do if you take too much Paxlovid

If you take more Paxlovid than you should, talk to your doctor or pharmacist. They will decide whether you need extra medical treatment. There is no special treatment for people who take too much Paxlovid.

How to take Paxlovid

Paxlovid is taken with food and should be taken exactly as your doctor or pharmacist tells you. It is important you take Paxlovid exactly as instructed. You must keep taking Paxlovid for as long as your doctor or pharmacist tells you.

Possible side effects

Paxlovid can have side effects. Paxlovid is a medicine with an ingredient that is a type of sugar. It may cause side effects in some people.

You should stop taking Paxlovid and talk to your doctor or pharmacist if you experience any of the following side effects:

- Vomiting
- Diarrhoea
- Feeling sick or feeling nausea
- Feeling weak, tired or weak
- Muscle pain
- Sweating
- Headache
- Swelling of the face, hands or feet
- Redness of the skin or a rash
- Feeling short of breath
- Heart rhythm problems
- Difficulty breathing
- Chest pain
- Difficulty swallowing
- Unusual tiredness
- Unusual bruising

If you have any other concerns about the side effects of Paxlovid, talk to your doctor or pharmacist.

How Paxlovid works

Paxlovid works by blocking a protein that helps the virus multiply. This stops the virus from spreading to the body. This can help your body to overcome the virus.

Possible side effects

Paxlovid may cause side effects in some people. Some people may experience side effects during treatment. Some people may experience side effects even after treatment has ended.

Possible side effects include:

- Nausea
- Vomiting
- Diarrhoea
- Headache
- Fatigue
- Rash
- Muscle pain
- Numbness or tingling

If you have any of these side effects, talk to your doctor or pharmacist.

What to do if you think you have a side effect

If you think you may have a side effect from Paxlovid, talk to your doctor or pharmacist. They can help you decide if you need medical attention and whether or not you need to stop taking Paxlovid.

How to store Paxlovid

Keep Paxlovid in a cool, dry place, away from direct heat and light. Keep it out of reach of children.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines that you no longer need.

Disposing of old medicines

If you have any further questions, ask your doctor or pharmacist. They can help you with any questions you may have.

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