

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

PAXLOVID 150 mg/100 mg film-coated tablets

Nirmatrelvir/Ritonavir

Contains sugar

Each 150 mg film-coated tablet of nirmatrelvir contains 176 mg of lactose.

Read all of this leaflet carefully before you start taking PAXLOVID

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, or other health care provider.
- PAXLOVID has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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 hospitalisation or death.

You must talk to a health care provider 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 hypersensitive (allergic) to nirmatrelvir, ritonavir or any of the other ingredients of PAXLOVID (listed in section 6)
- if you have severe liver disease
- if you have severe 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])
 - 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 (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, lomitapide (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)

Warnings and precautions

Take special care with PAXLOVID:

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

Liver disease

Tell your health care 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. PAXLOVID has not been studied in children and adolescents.

Other medicines and PAXLOVID

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

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

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 attention disorders, such as amphetamine derivatives e.g. methylphenidate and dexamfetamine
- medicines used to treat severe pain, such as morphine, fentanyl, methadone, buprenorphine, norbuprenorphine and other morphine-like medicines
- medicines 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, 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, 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 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, clarithromycin and sulfamethoxazole/trimethoprim
- medicines used to treat HIV infection, such as amprenavir, atazanavir, darunavir, fosamprenavir, efavirenz, maraviroc, raltegravir and zidovudine
- 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 amlodipine, diltiazem and nifedipine
- medicines used to treat high blood pressure in the blood vessels that supply the lungs, such as bosentan and riociguat
- 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 and everolimus
- medicines used to treat erectile dysfunction (also known as impotence), such as sildenafil and tadalafil
- medicines used as sedatives, hypnotics and sleeping agent, such as alprazolam, buspirone and zolpidem
- steroids including corticosteroids used to treat inflammation, such as budesonide, dexamethasone, fluticasone propionate, prednisolone and triamcinolone
- any of the following other specific medicines:
 - o bupropion (used for smoking cessation)
 - o oral or patch contraceptive containing ethinylestradiol used to prevent pregnancy
 - o 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)
 - o 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 health care provider. Your doctor can tell you if it is safe to take PAXLOVID with other medicines.

PAXLOVID with food and drink

PAXLOVID can be taken with or without food.

Pregnancy, breastfeeding and fertility

Pregnancy

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 or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Women of childbearing potential/contraception in females

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.

Breastfeeding

If you are breastfeeding or are planning to breastfeed, tell your health care provider before taking this medicine. Breastfeeding 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.

It is not always possible to predict to what extent PAXLOVID may interfere with your daily activities. You should ensure

that you do not engage in the above activities until you are aware of the measure to which PAXLOVID affects you.

PAXLOVID contains lactose

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

PAXLOVID contains sodium

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

3. How to take PAXLOVID

Do not share medicines prescribed for you with any other person.

Always take PAXLOVID exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

If you have kidney disease, please talk to your health care 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 and adolescents (under 18 years old).

If you take more PAXLOVID than you should

If you take too much PAXLOVID, call your health care 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 stop taking PAXLOVID

Even if you feel better, do not stop taking PAXLOVID 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

PAXLOVID can have side effects.

Not all side effects reported for PAXLOVID are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PAXLOVID, please consult your health care provider for advice.

Tell your doctor if you notice the following:

Frequent side effects

- Altered sense of taste

- Diarrhoea
- Vomiting

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via **the “6.04 Adverse Drug Reaction Reporting Form”**, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of PAXLOVID.

5. How to store PAXLOVID

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Do not refrigerate or freeze.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What PAXLOVID contains

- *The active substances in PAXLOVID 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 hypromellose, titanium dioxide, macrogol and iron oxide red.

- *The other ingredients in the ritonavir tablet are:*

Copovidone, sorbitan laureate, colloidal anhydrous silica, anhydrous calcium hydrogen phosphate and sodium stearyl fumarate.

The film-coating contains hypromellose, titanium dioxide, macrogol, hydroxypropyl cellulose, talc, colloidal anhydrous silica 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.

Holder of Certificate of Registration

Pfizer Laboratories (Pty) Ltd

85 Bute Lane

Sandton 2196

South Africa

Tel: (+27 11) 320 6000 / 0860 734 937 (Toll-free South Africa)

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