

## **WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET**

*This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.\**

*The medicine may be authorised for additional or different uses by national medicines regulatory authorities.*

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\* [https://extranet.who.int/prequal/sites/default/files/document\\_files/75%20SRA%20clarification\\_Feb2017\\_newtempl.pdf](https://extranet.who.int/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf)

## Information for the patient

**[CV024 trade name]<sup>†</sup>**  
Nirmatrelvir+Ritonavir

*If you are a carer or parent looking after the person who takes this medicine, use this leaflet to give the medicine correctly and take note of the warnings and 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 questions about the medicine, ask your health care provider.
- This medicine is for you only. Do not pass it on to others. It may harm them, even if their illness seems to be the same as yours.
- If you are concerned about any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

### What is in this leaflet

1. What [CV024 trade name] is and what it is used for
2. What you need to know before you take [CV024 trade name]
3. How to take [CV024 trade name]
4. Possible side effects
5. How to store [CV024 trade name]
6. Contents of the pack and other information

#### 1. What [CV024 trade name] is and what it is used for

The medicine [CV024 trade name] contains two active substances, nirmatrelvir and ritonavir, each in separate tablets. [CV024 trade name] is used for treating adults with COVID-19 who do not need treatment with oxygen. The medicine is used if you are more likely to get seriously ill with COVID-19.

COVID-19 is caused by a virus called SARS-CoV-2, a type of coronavirus. The active substance, nirmatrelvir, stops the virus multiplying in the body and this can help stop you becoming seriously ill and needing hospital treatment. The other active substance in the medicine, ritonavir, reduces the breakdown of nirmatrelvir and so increases its effect against the virus.

#### 2. What you need to know before you take [CV024 trade name]

##### Do not take [CV024 trade name]

- if you are allergic to nirmatrelvir, ritonavir, or to any of the other ingredients of this medicine (listed in section 6)
- if you are taking any of the following medicines. Taking [CV024 trade name] with these medicines may cause serious or life-threatening side effects or affect how [CV024 trade name] works:
  - Alfuzosin, silodosin (for treating prostate problems)
  - Amiodarone, dronedarone, eplerenone, flecainide, ivabradine, propafenone, quinidine (for treating heart conditions)
  - Apalutamide, neratinib, venetoclax (for treating cancer)

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<sup>†</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

- Avanafil, sildenafil, tadalafil, vardenafil (for treating men with erectile disorder; sildenafil and tadalafil are also used for treating high blood pressure in the lungs)
- Carbamazepine, phenobarbital, phenytoin (for treating epilepsy)
- Clorazepate, diazepam, estazolam, flurazepam, triazolam, midazolam (for relieving anxiety and sleeping trouble or for controlling convulsions)
- Clozapine, lurasidone, pimozide, quetiapine (for treating mental conditions such as abnormal thoughts or feelings, schizophrenia, and bipolar disorder)
- Colchicine (for treating gout)
- Dihydroergotamine, eletriptan, ergotamine, (for treating migraine headaches)
- Ergometrine, methylergometrine (for treating excessive bleeding after childbirth)
- Fusidic acid, rifampicin (for treating bacterial infections)
- Lomitapide, lovastatin, simvastatin (used to lower blood cholesterol)
- Ranolazine (for treating angina, a chest pain)
- St John's wort (*Hypericum perforatum*) (a herbal remedy for relieving depression and anxiety)
- Terfenadine (antihistamine for treating allergies such as hayfever)
- Tolvaptan (for treating some kidney disorders and correcting low sodium levels in the blood)
- Voclosporin (for treating conditions caused by overactive immune system)

There may be other medicines that you must not take with [CV024 trade name]. Talk to your health care provider about all the medicines you take before you start taking [CV024 trade name].

### **Warnings and precautions**

Talk to your health care provider about any concerns before you take [CV024 trade name].

### **Allergic reactions**

Allergic reactions, including severe allergic reactions (known as anaphylaxis), can happen in people taking [CV024 trade name], even after only 1 dose. Stop taking [CV024 trade name] and contact your health care provider right away if you get any of the following:

- trouble swallowing or breathing
- swelling of the tongue, mouth, and face
- throat tightness
- hoarseness
- itching
- skin rash

### **Liver disease**

Tell your health care provider if you have ever had liver disease. Liver injury can occur in patients taking the active substance ritonavir.

### **Kidney disease**

Tell your health care provider if you have ever had kidney disease.

### **High blood pressure**

Tell your doctor if you have high blood pressure. Some people taking this medicine may develop increases in their blood pressure, usually temporarily. Your health care provider may want to check your blood pressure during treatment.

### **Risk of developing HIV-1 resistance**

If you have untreated HIV infection, treatment with [CV024 trade name] may reduce how well some HIV medicines work.

### **Children and adolescents**

Do not give [CV024 trade name] to children and adolescents because there is not enough information on its use in children and adolescents aged under 18 years.

### **Other medicines and [CV024 trade name]**

Taking [CV024 trade name] at the same time as many other medicines can have unwanted effects. Tell your health care provider about **all** the medicines you are taking, have recently taken or might take. Your health care provider can tell you if you need to change any of your treatment.

Some medicines that may have unwanted effects with [CV024 trade name] are listed below.

- for cancer—afatinib, abemaciclib, apalutamide, ceritinib, dasatinib, encorafenib, fostamatinib, ibrutinib, nilotinib, vinblastine and vincristine
- for preventing blood clots (anticoagulants)—warfarin, rivaroxaban, dabigatran
- for epilepsy—divalproex (valproic acid and sodium valproate), lamotrigine
- for help to stop smoking—bupropion
- for allergies and hay fever—fexofenadine and loratadine
- for fungal infections—itraconazole and voriconazole
- for Cushing's syndrome (when the body produces high levels of steroid hormones)—ketoconazole
- for HIV infection—efavirenz, maraviroc, raltegravir and zidovudine
- for various infections—atovaquone, bedaquiline, clarithromycin, delamanid, erythromycin, fusidic acid, rifabutin, sulfamethoxazole/trimethoprim
- for some mental disorders—haloperidol, risperidone, thioridazine
- for reducing high blood pressure in the lungs—bosentan, riociguat
- for high blood pressure and preventing chest pain (angina)—amlodipine, diltiazem, lercanidipine, nifedipine
- for heart conditions—digoxin
- for hepatitis C virus infection—glecaprevir/pibrentasvir
- for lowering blood cholesterol—atorvastatin, fluvastatin, pravastatin, rosuvastatin
- for reducing effects of the immune system—ciclosporin, everolimus, sirolimus, tacrolimus
- for severe pain—buprenorphine, fentanyl, methadone, morphine, other morphine-like medicines, piroxicam
- for mood calming and help with sleeping—alprazolam, buspirone, zolpidem, and midazolam by injection (often used before surgery or some medical procedures)
- corticosteroids (often used to reduce inflammation)—betamethasone, budesonide, ciclesonide, dexamethasone, fluticasone, prednisolone, prednisone, triamcinolone
- for breathing problems such as asthma and chronic obstructive pulmonary disease—salmeterol, theophylline
- for relieving depression—amitriptyline, fluoxetine, imipramine, nortriptyline, paroxetine, sertraline
- for raising thyroid hormone levels—levothyroxine
- for family planning—contraceptive medicine containing ethinylestradiol

### **Pregnancy and breast-feeding**

If you are pregnant, think you may be pregnant or you are planning to have a baby, talk to your health care provider before taking this medicine.

There is not enough information to be sure that [CV024 trade name] is safe to take during pregnancy. If you are pregnant, your health care provider will help you decide if you can take [CV024 trade name].

You should take precautions not to become pregnant during treatment with [CV024 trade name]. Use contraception while taking [CV024 trade name] and for 7 days after completing [CV024 trade name].

[CV024 trade name] may reduce how well some hormone contraceptive medicines work and you and your partner should use another contraceptive method (such as a condom)—your health care provider can give you advice on the right contraception and how long to use it.

There is no information on taking [CV024 trade name] while breast-feeding. As a precaution, do not breast-feed your baby during treatment with [CV024 trade name] and for 7 days after you have finished taking the tablets.

### **Driving and using machines**

[CV024 trade name] is not likely to affect your ability to drive or operate machinery.

However, make sure you feel well enough to take on any skilled tasks.

### **This medicine contains Lactose**

Lactose is a source of glucose and galactose. The small amount of lactose in each dose is unlikely to cause symptoms of lactose intolerance. If, however, you have one of the rare genetic disorders galactosaemia, glucose-galactose intolerance or congenital lactase deficiency you must talk to your health care provider before taking this medicine.

This medicine may contain traces of cow's milk proteins. If you are allergic to cow's milk, talk to your health care provider before taking this medicine.

## **3. How to take [CV024 trade name]**

Always take this medicine exactly as your health care provider has told you. Take it regularly at around the same times each day. Check with your health care provider if you are not sure.

The [CV024 trade name] pack contains two types of tablets: one type contains the active substance nirmatrelvir and the other contains ritonavir. The usual recommended dose is 2 tablets of nirmatrelvir (Pink tablet) together with 1 tablet of ritonavir (Yellow tablet) twice daily, about 12 hours apart (in the morning and in the evening).

A course of treatment lasts 5 days. For each dose, take the nirmatrelvir and ritonavir together at the same time.

If you have kidney disease, talk to your health care provider about the right dose of [CV024 trade name] for you.

You can take [CV024 trade name] either with food or between meals.

Swallow the tablets whole with plenty of water. Do not chew, break, or crush the tablets.

### **If you take more [CV024 trade name] than you should**

If you take more [CV024 trade name] than you should, or if somebody else takes it, contact your health care provider straightaway.

### **If you forget to take [CV024 trade name]**

- You must not miss or skip doses of this medicine.
- If you forget to take a dose and your next regular dose is not due for at least 4 hours, take the dose at once and take the next dose at the usual time.
- If you forget to take a dose and your next regular dose is due in less than 4 hours, do not take the missed dose and instead take the next one at the usual time.
- Do not take a double dose to make up for a missed dose.
- If you are not sure what to do, ask your health care provider.

### **Do not stop taking [CV024 trade name]**

Do not stop taking [CV024 trade name] without first checking with your health care provider. Taking the medicine regularly and finishing the 5-day course gives you the best chance of not falling very ill with COVID-19.

#### 4. Possible side effects

Like all medicines, this medicine can cause side effects but not everybody gets them.

Common side effects that can affect up to 1 in 10 people are:

- diarrhoea
- vomiting
- nausea (feeling sick)
- altered sense of taste
- headache

Uncommon side effects that can affect up to 1 in 100 people are:

- allergic reactions (such as itching and skin rash)
- high blood pressure
- abdominal (belly) pain
- muscle pain

Rare side effects that can affect up to 1 in 1000 people

- severe allergic reactions (anaphylaxis), with swelling of the tongue, mouth and face, trouble swallowing or breathing, throat tightness, hoarseness)
- feeling generally unwell.

#### Reporting of side effects

If you get a side effect, talk to your health care provider. This includes side effects not listed in this leaflet. You may also be able to report such effects directly to your national reporting system if one is available. By reporting side effects, you can help to improve the available information on this medicine.

#### 5. How to store [CV024 trade name]

Do not store above 30°C. Store in the original container.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Do not use this medicine if you notice description of the visible signs of deterioration that it is different from the description below.

Do not throw away any medicines in wastewater or household waste. Ask your health care provider 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 [CV024 trade name] contains

##### Nirmatrelvir 150-mg tablets (Pink tablets)

- The active ingredient is nirmatrelvir
- The other ingredients of nirmatrelvir 150 mg are;

##### *Core tablet:*

Microcrystalline cellulose  
Lactose monohydrate  
Croscarmellose sodium  
Colloidal silicon dioxide  
Sodium stearyl fumarate

##### *Film coat:*

Titanium dioxide  
Hypromellose  
Macrogol/PEG  
Iron oxide red

**Ritonavir 100-mg tablets (Yellow tablets)**

- The active ingredient is ritonavir
- The other ingredients of ritonavir 100 mg are;

*Core tablet:*

Sorbitan monolaurate  
Copovidone  
Colloidal silicon dioxide  
Sodium chloride  
Sodium stearyl fumarate

*Film coat:*

Colloidal anhydrous silica  
Hypromellose  
Hydroxypropyl cellulose  
Iron oxide yellow  
Macrogol/PEG  
Polysorbate 80  
Talc  
Titanium dioxide

*Nirmatrelvir 150-mg film-coated tablets*

This medicine is essentially 'sodium-free'. It contains less than 1 mmol sodium (23 mg) per tablet.

*Ritonavir 100mg film-coated tablets*

Each tablet contains 3.82 mmol (87.76 mg) sodium, equivalent to about 4% of the WHO recommended maximum daily intake of 2 g sodium for an adult. To be taken into consideration by patients on a controlled sodium diet.

It is important to consider the contribution of excipients from all the medicines that the patient is taking.

**What [CV024 trade name] looks like and contents of the pack**

[CV024 trade name] consists of Nirmatrelvir 150-mg tablets co-packed together with Ritonavir 100-mg tablets.

*Nirmatrelvir 150-mg film-coated tablets*

[CV024 trade name] is pink, oval, film-coated tablets. They are biconvex (rounded on top and bottom) with a beveled edge. The tablets have 'T5' debossed (stamped into) on one side and are plain on the other side. No score line.

*Ritonavir 100mg film-coated tablets*

[CV024 trade name] is yellow, capsule-shaped, film-coated tablets. They are biconvex (rounded on top and bottom) with a flat edge. The tablets have 'M 163' debossed (stamped into) on one side and are plain on the other side. No score line.

The medicine is available in the following packs:

[CV024 trade name] is provided in aluminium-aluminium foil blister cards each containing 4 nirmatrelvir 150 mg film-coated tablets and 2 ritonavir 100 mg film-coated tablets. There are 5 such blister cards packed in a carton.

**Supplier and Manufacturer**

***Supplier***

Mylan Laboratories Limited  
Plot No.564/A/22, Road No.92,  
Jubilee Hills  
Hyderabad - 500096,  
Telangana, India.  
E-mail.: ProductSafety@viatris.com

***Manufacturer***

Mylan Laboratories Limited, FDF-I  
F- 4 & F-12, MIDC, Malegaon,  
Sinnar, Nashik - 422 113  
Maharashtra, India.

For any information about this medicine, contact the local representative of the supplier.

**This leaflet was last revised in January 2025**

*Detailed information on this medicine is available on the World Health Organization (WHO) website: <https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products>*