

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.

* https://extranet.who.int/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[CV016 trade name][†]
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 [CV016 trade name] is and what it is used for
2. What you need to know before you take [CV016 trade name]
3. How to take [CV016 trade name]
4. Possible side effects
5. How to store [CV016 trade name]
6. Contents of the pack and other information

1. What [CV016 trade name] is and what it is used for

The medicine [CV016 trade name] contains two active substances, nirmatrelvir and ritonavir, each in separate tablets.

[CV016 trade name] is used for treating patients with COVID-19 who are not yet seriously ill or struggling to breathe. The medicine is used if your immune system is less effective for any reason or you are elderly, very overweight, or have other conditions that make you 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 [CV016 trade name]

Do not take [CV016 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 medicines that may cause serious or life-threatening side effects with [CV016 trade name] or affect how [CV016 trade name] works.

[†] Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

See under '**Other medicines and [CV016 trade name]**', below, for more information, and make sure you talk to your health care provider about all the medicines you take before you start taking [CV016 trade name].

Warnings and precautions

Talk to your health care provider about any concerns before you take [CV016 trade name].

Allergic reactions

Allergic reactions, including severe allergic reactions (known as anaphylaxis) and severe skin rashes, can happen in people taking [CV016 trade name], even after only 1 dose. Stop taking [CV016 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, especially severe reddening, peeling or blistering with or without flu-like symptoms
- blisters or sores in your mouth or lips

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 resistance

If you have untreated HIV infection, treatment with [CV016 trade name] may reduce how well some HIV medicines work.

Children less than 6 years old

[CV016 trade name] is not intended for use in children less than 6 years of age or weighing less than 20 kg, because there is not yet enough information about its effectiveness and safety in this group.

Other medicines and [CV016 trade name]

Taking [CV016 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 (including any herbal products and supplements). Your health care provider can tell you if you need to change any of your treatment.

Some medicines should never be taken with [CV016 trade name] because of the risk of side effects or because they stop [CV016 trade name] from working properly. These include:

Alfuzosin, silodosin (for treating prostate problems)

Dronedarone, eplerenone, ivabradine, propafenone, quinidine, ranolazine (for treating

heart conditions)

Apalutamide, enzalutamide, neratinib, venetoclax (for treating cancer)

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, primidone (for treating epilepsy)

Clorazepate, diazepam, estazolam, flurazepam, triazolam, midazolam (for relieving anxiety and sleeping trouble or for controlling convulsions)

Cariprazine, 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)

Lomitapide, lovastatin, simvastatin (used to lower blood cholesterol)

Lumacaftor/ivacaftor (for cystic fibrosis)

Naloxegol (for treating constipation due to opioid painkillers)

Rifampicin, rifapentine (for treating tuberculosis [TB])

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)

Other medicines that may have unwanted effects with [CV016 trade name] are listed below, grouped by their most common uses.

for cancer—abemaciclib, afatinib, ceritinib, dasatinib, encorafenib, fostamatinib, ibrutinib, ivosidenib, nilotinib, vinblastine and vincristine

for severe pain—buprenorphine, fentanyl, methadone, morphine, oxycodone, pethidine, piroxicam

for epilepsy—clonazepam, divalproex (valproic acid and sodium valproate), lamotrigine

for help to stop smoking—bupropion

for allergies and hayfever (antihistamines)—fexofenadine and loratadine

for Cushing's syndrome (when the body produces high levels of steroid hormones)—ketoconazole

for HIV infection—bictegravir/emtricitabine/tenofovir, efavirenz, maraviroc, raltegravir and zidovudine

for fungal infections—itraconazole and voriconazole

for hepatitis C virus infection—glecaprevir/pibrentasvir, sofosbuvir/velpatasvir/voxilaprevir

for various other infections—albendazole, atovaquone, bedaquiline, clarithromycin, delamanid, erythromycin, fusidic acid, rifabutin, sulfamethoxazole/trimethoprim

for relieving depression—amitriptyline, fluoxetine, imipramine, nortriptyline, paroxetine, sertraline

for some mental disorders—aripiprazole, brexpiprazole, clozapine, haloperidol, risperidone, thioridazine

for mood calming and help with sleeping—alprazolam, buspirone, zolpidem, and midazolam by injection (often used before surgery or some medical procedures)

for circulation problems including high blood pressure and preventing chest pain (angina)—amlodipine, cilostazol, diltiazem, felodipine, lercanidipine, nicardipine, nifedipine, verapamil

for reducing high blood pressure in the lungs—bosentan, riociguat

for other heart conditions—amiodarone, digoxin, disopyramide, flecainide

for lowering blood cholesterol—atorvastatin, fluvastatin, pravastatin, rosuvastatin

for preventing blood clots (anticoagulants)—apixaban, dabigatran, rivaroxaban, warfarin

for reducing effects of the immune system—cyclosporin, everolimus, sirolimus, tacrolimus

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 cystic fibrosis—elexacaftor/tezacaftor/ivacaftor, ivacaftor (given separately), tezacaftor/ivacaftor

for diabetes (type 2)—saxagliptin

for thyroid problems—levothyroxine

for urinary problems—darifenacin, solifenacin

for prostate enlargement—tamsulosin

for family planning—contraceptive medicines containing ethinylestradiol

There may be other medicines not in this list that can have unwanted effects when used with [CV016 trade name], so it is **important** that you discuss any other medicines you take or are thinking of taking with your health care provider.

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.

Being pregnant may increase your risk of developing severe symptoms of COVID-19, so this medicine has been used in pregnancy, but it is not clear whether this can have any effect on the unborn baby. If you are pregnant, your health care provider will help you decide if you can take [CV016 trade name].

You should take precautions not to become pregnant during treatment with [CV016 trade name]. Use contraception while taking [CV016 trade name] and for 7 days after completing [CV016 trade name].

[CV016 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 [CV016 trade name] while breast-feeding. Very small amounts of the medicine enter your breast milk, so as a precaution, do not breast-feed your baby during treatment with [CV016 trade name] and for 2 days after you have finished taking the tablets.

Driving and using machines

[CV016 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 [CV016 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 [CV016 trade name] pack contains two types of tablets: one type contains the active substance nirmatrelvir and the other contains ritonavir. The usual recommended dose in patients 6 years of age or older depends on weight as follows

Patient's weight	Dose
40 kg or more	2 tablets of nirmatrelvir (yellow tablet) together with 1 tablet of ritonavir (white tablet) twice daily, about 12 hours apart (in the morning and in the evening)
20 to less than 40 kg	1 tablet of nirmatrelvir (yellow tablet) together with 1 tablet of ritonavir (white tablet) twice daily, about 12 hours apart (in the morning and in the evening). In this case there may be some tablets left over in the pack at the end of the course

This medicine is not recommended for children under 6 years of age or weighing less than 20 kg.

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**, your dose of this medicine may need to be lower. Talk to your health care provider about the right dose of [CV016 trade name] for you. Some tablets may be left in the pack at the end of the course.

If you need haemodialysis, on days you have it you should take your dose of [CV016 trade name] after dialysis is over.

You can take [CV016 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 [CV016 trade name] than you should

If you take more [CV016 trade name] than you should, or if somebody else takes it, contact your health care provider straightaway.

If you forget to take [CV016 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 [CV016 trade name]

Do not stop taking [CV016 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
- 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)
- itching
- severe skin rashes, with pain, blistering and peeling, affecting mouth, eyes and genitals, accompanied by flu-like symptoms
- 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 [CV016 trade name]

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

Do not store above 30°C.

Do not use this medicine after the expiry date stated on blister and carton 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 or 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

- The active ingredient of nirmatrelvir tablet is 150 mg nirmatrelvir.
- The active ingredient of ritonavir tablet is 100 mg ritonavir.
- The other ingredients of [CV016 trade name] are:
Nirmatrelvir 150 mg film-coated tablets: microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, colloidal silicon dioxide, sodium stearyl fumarate, hypromellose, titanium dioxide, macrogol/PEG and iron oxide yellow.
Ritonavir 100 mg film-coated tablets: colloidal silicon dioxide, anhydrous dibasic calcium phosphate, copovidone, sorbitan monolaurate, sodium stearyl fumarate, titanium dioxide, hypromellose, macrogol/PEG and polysorbate 80.

There is too little sodium in this medicine to have any effect, even if you are on a low-sodium diet.

What [CV016 trade name] looks like and contents of the pack

Nirmatrelvir 150mg film-coated tablets

Yellow, oval, film-coated tablets. They are biconvex (rounded on top and bottom) with a flat edge. The tablets have ‘150’ debossed (stamped into) one side and are plain on the other side.

Ritonavir 100mg film-coated tablets

White, oval, film-coated tablets. They are biconvex (rounded on top and bottom) with a flat edge. The tablets have “54” debossed (stamped into) on one side and “247” on the other side.

Pack size

Silvery white plastic and aluminium (PA/Alu/PVC) on aluminium foil blister cards, each containing 4 nirmatrelvir 150 mg tablets and 2 ritonavir 100 mg tablets. Available in cartons of 5 × 6 tablets.

Supplier and Manufacturer

Supplier

Zhejiang Huahai Pharmaceutical Co., Ltd.
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For any information about this medicine, contact the local representative of the supplier:

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