

Brightside Specialty Pharmacy

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Patient Education for PAXLOVID 300-100 MG PACK (EUA)

.....Education Section.....

IMPORTANT:

HOW TO USE THIS INFORMATION: This is a summary and

does NOT have all possible information about this product. This information does not assure that this product is safe, effective, or appropriate for you. This information is not individual medical advice and does not substitute for the advice of your health care professional. Always ask your health care professional for complete information about this product and your specific health needs.

NIRMATRELVIR/RITONAVIR - ORAL

COMMON BRAND NAME(S):

Paxlovid

USES:

The combination of nirmatrelvir tablets and ritonavir

tablets is a product that the FDA is allowing to be given for emergency use to treat COVID-19. The product is also approved to be used in Canada to treat COVID-19. It is used by people who have recently tested positive for coronavirus, have had mild to moderate symptoms for no more than 5 days and are not hospitalized. To receive this product you must also be at high risk for COVID-19 complications due to older age, obesity, or ongoing medical conditions (such as lung or heart disease or diabetes, among others). Talk to your doctor about the risks and benefits of treatment with nirmatrelvir and ritonavir.

Nirmatrelvir is a SARS-CoV-2 main protease inhibitor. It works by preventing the growth of the virus that causes COVID-19. Ritonavir increases ("boosts") the levels of nirmatrelvir. This helps nirmatrelvir work better. More information about nirmatrelvir and ritonavir is available from the FDA Fact Sheet for Patients, Parents, and Caregivers for Emergency Use and from the Health Canada Patient Medication Information sheet.

There is limited information about how safe and effective the combination of nirmatrelvir and ritonavir is for treating COVID-19. Study results show that nirmatrelvir and ritonavir may help people who have recently tested positive for coronavirus stay out of the hospital. This product is not for use by people who are hospitalized due to COVID-19.

The information in this document reflects emerging data, which is evolving and subject to reassessment. Users should be aware of these considerations in their review of nirmatrelvir and ritonavir, and it is always the responsibility of treating practitioners to exercise independent judgement in making care decisions.

HOW TO USE:

Take this medication by mouth with or without food

as directed by your doctor, usually once in the morning and once in the evening for 5 days. Swallow the tablets whole. Do not chew, break, or crush the tablets. The dosage is based on your medical condition and response to treatment.

Continue to take this medication for the full time prescribed. Stopping the medication too early may allow the virus to continue to grow, which may result in a return of the infection or failure to protect you from the virus.

Tell your doctor if your condition lasts or gets worse.

SIDE EFFECTS:

Changes in taste, diarrhea, high blood pressure,

or muscle pain may occur. If any of these effects last or get worse, tell your healthcare professional promptly.

Tell your doctor right away if you have any serious side effects, including: signs of liver problems (such as nausea/vomiting that doesn't stop, loss of appetite, stomach/abdominal pain, yellowing eyes/skin, dark urine).

A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

Information is limited and it is unknown at this time if nirmatrelvir and ritonavir cause other serious side effects. This is not necessarily a complete list of possible side effects.

Contact your doctor for medical advice about side effects.

PRECAUTIONS:

Before taking this medication, tell your doctor if

you have any allergies. This product may contain inactive

ingredients which can cause allergic reactions or other problems.

Limited information is known at this time about other medical conditions that may affect how nirmatrelvir and ritonavir work, or how nirmatrelvir and ritonavir may affect other medical conditions.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: kidney disease, liver disease, HIV infection.

To avoid spreading the virus, you should continue to take precautions such as self-isolation, wearing a mask, social distancing (physical distancing), washing hands, and not sharing personal items.

Tell your doctor if you are pregnant or think you are pregnant. The combination of nirmatrelvir and ritonavir should be used during pregnancy only if the possible benefits are greater than the possible risks.

It is unknown if nirmatrelvir passes into breast milk. Ritonavir does pass into breast milk. The risks of breast-feeding while infected with COVID-19 and while using this product should be discussed with the doctor.

DRUG INTERACTIONS:

Drug interactions may change how your

medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval.

A product that may interact with this drug is: orlistat.

Ritonavir can slow down or speed up the removal of other medications from your body, which may affect how they work. Examples of affected drugs include alfuzosin, antiarrhythmics (such as amiodarone, flecainide, propafenone, quinidine), azole antifungals (such as voriconazole), certain benzodiazepines (midazolam, triazolam), certain "blood thinners" (such as rivaroxaban, warfarin), eletriptan, drugs to treat erectile dysfunction-ED or pulmonary hypertension (such as avanafil, sildenafil), ergot alkaloids (such as dihydroergotamine, ergonovine, ergotamine, methylergonovine), lurasidone, certain opioid pain medications (such as fentanyl, meperidine), pimozide, ranolazine, salmeterol, "statin" cholesterol drugs (such as simvastatin, lovastatin), among others.

Other medications can affect the removal of ritonavir from your body, which may affect how ritonavir works. Examples include apalutamide, rifampin, St. John's wort, drugs used to treat seizures (such as carbamazepine, phenobarbital, phenytoin), among others.

This medication may decrease the effectiveness of hormonal birth control (containing ethinyl estradiol) such as pills, patch, or ring. This could cause pregnancy. Discuss with your doctor or pharmacist if you should use reliable backup birth control methods while using this medication. Also tell your doctor if you have any new spotting or breakthrough bleeding, because these may be signs that your birth control is not working well.

OVERDOSE:

If someone has overdosed and has serious symptoms such

as passing out or trouble breathing, call 911. Otherwise, call a poison control center right away. US residents can call their local poison control center at 1-800-222-1222. Canada residents can call a provincial poison control center.

NOTES:

Do not share this medication with others.

Lab and/or medical tests (such as liver tests, kidney tests) should be done while you are taking this medication. Keep all medical and lab appointments. Consult your doctor for more details.

MISSED DOSE:

If you miss a dose, take it as soon as you remember

if it is less than 8 hours after the time you would usually take it. If more than 8 hours have passed, skip the missed dose. Take your next dose at the regular time. Do not double the dose to catch up.

STORAGE:

Store at room temperature away from light and moisture.

Do not store in the bathroom. Keep all medications away from children and pets.

Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company.

Information last revised April 2022.

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