

Drug Information Sheet("Kusuri-no-Shiori")

Internal

Revised: 10/2022

The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

Brand name:PaxlovidPACK

Active ingredient:Nirmatrelvir
Ritonavir

Dosage form:Nirmatrelvir: pale red tablet, major axis; 17.5 mm, minor axis; 8.5 mm, thickness; 5.7 mm/Ritonavir: white to faintly yellowish white tablet, major axis; approx. 17 mm, minor axis; approx. 9 mm, thickness; approx. 6 mm

Imprint or print on wrapping:PAXLOVID(ritonavir tablet(100mg), nirmatrelvir tablet(150mg)), Morning Dose or Evening Dose, PFE, 3CL, NK



Effects of this medicine

This medicine is a combination of nirmatrelvir and ritonavir.

Nirmatrelvir inhibits the SARS-CoV-2 main protease and thereby suppresses the reproduction of the virus. Ritonavir inhibits the metabolism of nirmatrelvir and thereby increases plasma level of nirmatrelvir.

It is usually used to treat SARS-CoV-2 infection.

The following patients may need to be careful when using this medicine.Be sure to tell your doctor and pharmacist.

- If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines or foods.
If you have: HIV infection, renal dysfunction or liver dysfunction.
- If you are pregnant or breastfeeding.
- If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

Dosing schedule (How to take this medicine)

- Your dosing schedule prescribed by your doctor is((to be written by a healthcare professional))
- In general, for adults and children 12 years or over with body weight 40 kg or over, take 2 tablets of nirmatrelvir (300 mg of the active ingredient) concomitantly with one tablet of ritonavir (100 mg of the active ingredient) at a time, twice a day, for 5 days. Strictly follow the instructions.
- Swallow the tablet without chewing, cracking or crushing.
- If you miss a dose and notice it within 8 hours after the scheduled dosing time, take the missed dose as soon as possible. If you notice it more than 8 hours after the scheduled dosing time, skip the missed dose and follow your regular dosing schedule. You should never take two doses at one time.
- If you accidentally take more than your prescribed dose, consult with your doctor or pharmacist.
- Do not stop taking this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

- Refrain from taking any food containing St. John's Wort (a kind of herb) or tobacco (smoking), since it may diminish medicinal effects.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include dysgeusia and diarrhea/loose stool. If any of these symptoms occur, consult with your doctor or pharmacist.

The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets. If any of these symptoms occur, stop taking this medicine and see your doctor immediately.

- general malaise, loss of appetite, nausea [liver dysfunction]
- high fever, lip erosion/eye bloodshot/sore throat, redness/blister of skin/mucosa [toxic epidermal necrolysis (TEN), oculomucocutaneous syndrome]
- breathing difficulty, hives, general itch [anaphylaxis]

The above symptoms do not describe all the adverse reactions to this medicine. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.

Storage conditions and other information

- Keep out of reach of children. Store at room temperature (1 to 30 degrees Celsius), away from direct sunlight and moisture.

•Discard the remainder. Do not store them. If you do not know how to dispose of the unused medicines, seek advice of your pharmacy or medical institution. Do not give the unused medicines to others.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.