



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Paxlovid (*nirmatrelvir* / *ritonavir*)

An overview of Paxlovid and why it is authorised in the EU

What is Paxlovid and what is it used for?

Paxlovid is an antiviral medicine used to treat coronavirus disease 2019 (COVID-19) in adults and children from 6 years of age who weigh at least 20 kg. It is used in patients who do not require supplemental oxygen and are at increased risk of the disease becoming severe.

Paxlovid contains two active substances, nirmatrelvir and ritonavir, in two different tablets.

How is Paxlovid used?

Paxlovid can only be obtained with a prescription. For adults and children aged 6 years and older weighing at least 40 kg, the recommended dose is two tablets of nirmatrelvir and one tablet of ritonavir, to be taken together by mouth twice daily for 5 days. For children aged 6 years and older weighing at least 20 kg and less than 40 kg, the recommended dose is one tablet of nirmatrelvir and one tablet of ritonavir, to be taken together by mouth twice daily for 5 days. Paxlovid should be given as soon as possible after a diagnosis of COVID-19 has been made and within 5 days of the start of symptoms.

For more information about using Paxlovid, see the package leaflet or contact your doctor or pharmacist.

How does Paxlovid work?

Paxlovid is an antiviral medicine that reduces the ability of SARS-CoV-2 (the virus that causes COVID-19) to multiply in the body. The active substance, nirmatrelvir, blocks the activity of an enzyme needed by the virus to multiply. Paxlovid also contains a low dose of ritonavir, which slows the breakdown of nirmatrelvir, enabling it to remain longer in the body at levels that affect the multiplication of the virus. Together, the two active substances can help the body to overcome the infection and prevent the disease from becoming severe.

What benefits of Paxlovid have been shown in studies?

A main study involving adults with COVID-19 and at least one underlying condition putting them at risk of severe COVID-19 looked at the effects of Paxlovid on rate of hospitalisation or death within 28 days

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of treatment when compared with placebo (a dummy treatment). The analysis was done in patients who received Paxlovid within 5 days after COVID-19 symptoms began and who did not receive nor were expected to receive treatment with antibodies. Over the month following treatment, the rate of hospitalisation or death was 0.8% (8 out of 1,039) for patients who received Paxlovid, compared with 6.3% (66 out of 1,046) for those who received placebo. There were no deaths in the Paxlovid group and 12 deaths in the placebo group.

The majority of patients in the study were infected with the Delta variant. Based on laboratory studies, Paxlovid is also expected to be active against Omicron and other variants.

A second main study involved 77 children, aged from 6 to 17 years and weighing at least 20 kg, with COVID-19 and at least one underlying condition putting them at risk of severe COVID-19. This study showed that Paxlovid behaves in a similar way in children and adults.

What are the risks associated with Paxlovid?

For the full list of restrictions and side effects with Paxlovid, see the package leaflet.

The most common side effects with Paxlovid (which may affect less than 1 in 10 people) include dysgeusia (taste disturbance), diarrhoea, headache and vomiting.

Paxlovid must not be used together with medicines that are harmful at high levels in the blood and whose breakdown in the body is reduced by ritonavir. Paxlovid must also not be taken by people who have just stopped these medicines as some of the medicine may still remain in the body. Paxlovid must also not be taken with medicines that may reduce its effectiveness or by patients who are taking St John's wort (a herbal preparation used to treat depression). To identify interactions with ritonavir, a drug interaction tool is available on the website of the company marketing Paxlovid which can be accessed through a QR code in the product information and outer carton.

Why is Paxlovid authorised in the EU?

Paxlovid was shown to be effective at reducing the risk of hospitalisation or death in adults with COVID-19 who are at increased risk of the disease becoming severe. Because Paxlovid was shown to behave similarly in adults and in children from 6 years of age who weigh at least 20 kg, it is expected to have similar effectiveness in children. The safety profile of Paxlovid was favourable and side effects were generally mild. The potential for ritonavir to interfere with other medicines was a concern, but this has been addressed through advice included in Paxlovid's product information. The European Medicines Agency concluded that Paxlovid's benefits are greater than its risks and it can be authorised for use in the EU.

Paxlovid was originally given 'conditional authorisation'. The authorisation was then switched to standard authorisation as the company provided additional data requested by the Agency.

What measures are being taken to ensure the safe and effective use of Paxlovid?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Paxlovid have been included in the summary of product characteristics and the package leaflet, including a link to a drug interaction tool to identify interactions with ritonavir.

As for all medicines, data on the use of Paxlovid are continuously monitored. Suspected side effects reported with Paxlovid are carefully evaluated and any necessary action taken to protect patients.

Other information about Paxlovid

Paxlovid received a conditional marketing authorisation valid throughout the EU on 28 January 2022. The conditional marketing authorisation was switched to a standard marketing authorisation on 24 February 2023.

Further information on Paxlovid can be found on the Agency's website:

ema.europa.eu/medicines/human/EPAR/paxlovid.

This overview was last updated in 11-2025.