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Paxlovid (*PF-07321332 / ritonavir*)

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

What is Paxlovid and what is it used for?

Paxlovid is a medicine used for treating COVID-19 in adults who do not require supplemental oxygen and who are at increased risk of the disease becoming severe.

Paxlovid contains two active substances, PF-07321332 and ritonavir, in two different tablets.

How is Paxlovid used?

Paxlovid can only be obtained with a prescription. The recommended dose is two tablets, each containing 150 mg PF-07321332, plus one tablet containing 100 mg ritonavir, to be taken together by mouth twice a day 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 PF-07321332 blocks the activity of an enzyme needed by the virus to multiply. Paxlovid also contains a low dose of the medicine ritonavir, which slows the breakdown of PF-07321332, enabling it to remain longer in the body at levels that affect the multiplication of the virus. Together, the active substances can help the body to overcome the virus infection, and prevent the disease becoming severe.

What benefits of Paxlovid have been shown in studies?

A main study involving patients 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 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

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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.

What are the risks associated with Paxlovid?

The most common side effects with Paxlovid (which may affect less than 1 in 10 people) are 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.

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

Why is Paxlovid authorised in the EU?

Paxlovid was shown to be effective at reducing the risk of hospitalisation or death in patients with COVID-19 at increased risk of the disease becoming severe. The safety profile of Paxlovid was favourable and side effects were generally mild. However, the well-known effect of ritonavir on other medicines was a concern and advice is 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' because there was more evidence to come about the medicine. As the company has supplied the additional information necessary, the authorisation has been switched from conditional to full authorisation.

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. This was switched to a full 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

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