swissmedic

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Paxlovid® (active substances: nirmatrelvir, ritonavir)

Temporary authorisation in Switzerland: 15 June 2022

Medicinal product (tablets) for the treatment of COVID-19 in adults

About the medicinal product

The medicinal product Paxlovid contains the active substances nirmatrelvir and ritonavir and is taken in the form of tablets.

Paxlovid is an antiviral medicine (antiviral agent). It is used for the treatment of adults with COVID-19, which is caused by the SARS-CoV-2 coronavirus. Paxlovid is only used for patients who do not require oxygen therapy or hospitalisation due to COVID-19 and who are at increased risk of the disease becoming severe.

Paxlovid is not intended as a replacement for vaccination against COVID-19.

The symptoms of COVID-19 range from mild infections to severe disease. In approx. 20% of affected patients the symptoms are severe or even critical, potentially leading to death. Certain characteristics (e.g. advanced age) increase the risk of the disease becoming severe.

Mode of action

Paxlovid is a combination product consisting of two active substances, nirmatrelvir and ritonavir.

Nirmatrelvir is an inhibitor of the most important proteolytic enzyme[1] of the coronavirus. Nirmatrelvir binds to the active site of this enzyme, preventing the cleavage of proteins that play a decisive role in the replication of the virus.

Ritonavir is also a proteolytic enzyme and enhances the action of nirmatrelvir.

Paxlovid thus prevents the virus from replicating in the body's cells. This can help the body to overcome the viral infection and avoid severe disease.

[1] Proteolytic enzyme: Proteolytic enzymes, also referred to as peptidases or proteases, are enzymes that can split (cleave) and break down proteins.

Indication

Paxlovid, containing the active substances nirmatrelvir and ritonavir, is a prescription-only medicine.

The active substances are available as separate tablets in doses of 150 mg (nirmatrelvir) and 100 mg (ritonavir). The recommended dosage for adults is 300 mg nirmatrelvir (two tablets) and 100 mg ritonavir (one tablet) taken together every 12 hours.

Treatment is given for a period of five days.

Treatment with Paxlovid should be started as soon as possible after the positive COVID-19 test result has been obtained.

Paxlovid should be used according to the official recommendations and taking into account the local epidemiological data on the COVID-19 variants in circulation.

Efficacy

Swissmedic took the available interim results of the ongoing EPIC-HR trial into account when evaluating the efficacy of Paxlovid in reducing hospital admissions and deaths due to COVID-19.

This trial enrolled adult patients with COVID-19 that had been confirmed by laboratory testing. The trial subjects had at least one risk factor, such as diabetes, for disease progression or severe disease.

The subjects were given either Paxlovid or placebo (dummy medication) every 12 hours for five days.

The primary objective of the trial was to compare the efficacy of Paxlovid versus placebo in the treatment of COVID-19 in patients who were not receiving inpatient care and who were at increased risk of progressing to severe disease.

The primary efficacy endpoint[2] was the proportion of participants with hospital admission due to COVID-19 or death by day 28 of the trial. Treatment with Paxlovid was started within five days of the symptoms developing.

The results show an absolute reduction of the risk of severe COVID-19 for Paxlovid of 5.5% compared with placebo (0.8% versus 6.3%). Furthermore, none of the patients in the group treated with Paxlovid died, while there were 12 deaths in the placebo group

Precautions, undesirable effects & risks

Paxlovid must not be used in those who are hypersensitive to the active substances or any of the excipients.

The most common undesirable effects (affecting between 1 and 10 of 100 people treated) are taste disturbance, diarrhoea, vomiting and headache.

A large number of medicines interact with Paxlovid. Patients must therefore show their doctor and pharmacist a list of the medicines they are taking.

All precautions, risks and other possible side effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

[2] Primary efficacy endpoint: The primary endpoint is the main objective of the trial determined before the trial starts. If the primary endpoint is reached or exceeded, the trial proves that a treatment is effective. Secondary endpoints, on the other hand, refer to other effects that do not clearly prove efficacy or that do not allow any clear conclusions to be drawn about the actual target criterion (primary endpoint).

Why the medicinal product has been authorised

There is a need for oral medicines to prevent serious complications of COVID-19 that are easy to administer and have mechanisms of action different to those of conventional medicinal products.

In the pivotal EPIC-HR trial, Paxlovid reduced the number of hospital admissions due to COVID-19 and all-cause deaths significantly up to day 28 of the trial.

Taking all the risks and precautions into account, and based on the available data, the benefits of Paxlovid outweigh the potential safety risks.

Swissmedic authorised the medicinal product Paxlovid temporarily in Switzerland (in accordance with Art. 9a TPA) since not all clinical trials were available or had been concluded at the time of authorisation. The temporary authorisation is contingent on the timely submission of the data requested by Swissmedic. Once these authorisation conditions have been met, the temporary authorisation can be converted into an ordinary authorisation in the event of a positive benefit-risk assessment of the results.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Paxlovid®

Information for patients (package leaflet): Information for patients Paxlovid®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.