swissmedic

Summary report on authorisation dated 3 July 2026

Paxlovid® (active substances: nirmatrelvir, ritonavir)

Indication extension in Switzerland: 27 March 2026

Film-coated tablets for the treatment of COVID-19 in children 6 years of age and older weighing at least 20 kg

About the medicinal product

Paxlovid contains the active substances nirmatrelvir and ritonavir.

Paxlovid was first authorised by Swissmedic on 15 June 2022 for the treatment of coronavirus disease 2019 (COVID-19) in adults who do not require oxygen therapy or hospitalisation due to COVID-19 and who are at increased risk of progressing to severe COVID-19.

The current indication extension means that Paxlovid can now also be used for the treatment of COVID-19 in children 6 years of age and older weighing at least 20 kg who do not require oxygen therapy or hospitalisation due to COVID-19 and who are at increased risk of progressing to severe COVID-19.

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

Mode of action

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.

Administration

Paxlovid 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 dose for children 6 years of age and older weighing at least 20 kg and less than 40 kg is 150 mg nirmatrelvir (one nirmatrelvir 150 mg tablet) together with 100 mg ritonavir (one ritonavir 100 mg tablet) every 12 hours.

The recommended dose for children 6 years of age and older weighing at least 40 kg is 300 mg nirmatrelvir (two nirmatrelvir 150 mg tablets) together with 100 mg ritonavir (one ritonavir 100 mg tablet) every 12 hours.

Treatment is given for a period of five days.

Efficacy

The efficacy of Paxlovid for the treatment of paediatric patients with COVID-19 is based mainly on the studies with adults, which have shown Paxlovid to be effective. A further study, named EPIC-PEDS, investigated the use of Paxlovid in non-hospitalised children with risk factors for progression to severe disease. The clinical results showed no COVID 19-related hospitalisations or deaths from any cause for any of the study participants up to Day 28. A comparison with the results for adults is only possible to a limited extent, since the recording of COVID-19 signs and symptoms differed between the studies.

Precautions, undesirable effects, & risks

Paxlovid must not be used in those who are hypersensitive to one of 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, nausea, vomiting and headache.

Paxlovid influences enzymes that regulate the metabolism of medicines. This can raise or lower the concentrations of medicines taken at the same time and thereby influence their efficacy and safety. Since a large number of medicines interact with Paxlovid, patients must show their doctor and pharmacist a list of medicines they are taking.

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

Why the medicinal product has been authorised

COVID-19 is a disease that can be particularly dangerous for certain risk groups, for example children and adolescents with pre-existing illnesses. Paxlovid offers an oral treatment option for these patients who do not need to be hospitalised.

The studies show that Paxlovid effectively lowers the viral load, potentially reducing the severity of the disease.

Taking all the risks and precautions into account, and based on the available data, the benefits of Paxlovid outweigh the risks. Swissmedic has therefore authorised the indication extension for Paxlovid, containing the active substances nirmatrelvir and ritonavir, in Switzerland for children 6 years of age and older weighing at least 20 kg who do not require oxygen therapy or hospitali-

sation due to COVID-19 and who are at increased risk of progressing to severe COVID-19.

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 Summary report on authorisation.

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