16 October 2025
EMA/CHMP/308348/2025
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (post authorisation)**

# Paxlovid

nirmatrelvir / ritonavir

On 16 October 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending a change to the terms of the marketing authorisation for the medicinal product Paxlovid. The marketing authorisation holder for this medicinal product is Pfizer Europe MA EEIG.

The CHMP adopted a change to the existing indication as follows:[2]

> Paxlovid is indicated for the treatment of coronavirus disease 2019 (COVID-19) in adults **and paediatric patients 6 years of age and older weighing at least 20 kg** who do not require supplemental oxygen and who are at increased risk for progressing to severe COVID 19 (see section 5.1).

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] New text in bold

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