10 December 2020
EMA/669235/2020
Committee for Medicinal Products for Human Use (CHMP)

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

# Veklury

remdesivir

On 10 December 2020, 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 Veklury. The marketing authorisation holder for this medicinal product is Gilead Sciences Ireland UC.

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

> Veklury is indicated for the treatment of coronavirus disease 2019 (COVID-19) in adults and adolescents (aged 12 years and older with body weight at least 40 kg) with pneumonia requiring supplemental oxygen **(low- or high-flow oxygen or other non-invasive ventilation at start of treatment)**.

Detailed recommendations for the use of this product are described in the product information (PI), which is published in English here.

The updated PI will be published in the revised European public assessment report (EPAR) 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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