



15 September 2022
EMA/759875/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Evusheld

tixagevimab / cilgavimab

On 15 September 2022, 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 Evusheld. The marketing authorisation holder for this medicinal product is AstraZeneca AB.

The CHMP adopted an extension to the existing indication for Evusheld to include the treatment of COVID-19 in adults and adolescents.

For information, the full indication for Evusheld will be as follows:²

Pre-exposure prophylaxis

Evusheld is indicated for the pre-exposure prophylaxis of COVID-19 in adults and adolescents aged 12 years and older weighing at least 40 kg (see sections 4.2, 5.1 and 5.2).

Treatment

Evusheld is indicated for the treatment of adults and adolescents (aged 12 years and older weighing at least 40 kg) with COVID-19, who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19 (see sections 4.2, 5.1 and 5.2).

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available 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

