26 March 2026
EMADOC-1700519818-3006977
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Capvaxive

pneumococcal polysaccharide conjugate vaccine (21-valent)

On 26 March 2026, 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 Capvaxive. The marketing authorisation holder for this medicinal product is Merck Sharp & Dohme B.V.

The CHMP adopted an extension of the existing indication as follows:[2]

> CAPVAXIVE is indicated for active immunisation for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* in individuals 18 years of age and older.
>
> **CAPVAXIVE is indicated for active immunisation for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* in children and adolescents 2 to less than 18 years of age who previously completed a primary paediatric pneumococcal vaccination regimen.**
>
> See sections 4.4 and 5.1 for information on protection against specific pneumococcal serotypes.
>
> The use of CAPVAXIVE should be in accordance with official recommendations.

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] Summary 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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