30 January 2025
EMA/24781/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Capvaxive

pneumococcal polysaccharide conjugate vaccine (21-valent)

On 30 January 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Capvaxive, a vaccine intended for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae*.

The applicant for this medicinal product is Merck Sharp & Dohme B.V.

Capvaxive will be available as a solution for injection in pre-filled syringe. The active substance of Capvaxive is pneumococcal polysaccharide conjugate vaccine (21-valent), a pneumococcal vaccine (ATC code: J07AL02), which elicits an immune response against the 21 serotypes contained in the product.

The benefit of Capvaxive is the presumed protection against pneumococcal disease based on immunobridging data. The most common side effects with Capvaxive are pain at the injection site, fatigue, headache and myalgia.

The full indication is:

> 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.
>
> 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 summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after 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

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