14 October 2021
EMA/CHMP/539313/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Vaxneuvance

pneumococcal polysaccharide conjugate vaccine (15-valent, adsorbed)

On 14 October 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Vaxneuvance, intended for prophylaxis against pneumococcal pneumonia and associated invasive disease.

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

Vaxneuvance will be available as suspension for injection. The active substance of Vaxneuvance is pneumococcal polysaccharide conjugate vaccine (15-valent, adsorbed), a vaccine (ATC code: J07AL02) eliciting an immune response to all 15 serotypes contained in the product.

The benefits of Vaxneuvance are the presumed protection against pneumococcal disease (based on immunobridging data). The most common side effects are injection site pain, fatigue and headache.

The full indication is:

> Vaxneuvance 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 Vaxneuvance 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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union