



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 December 2021
EMA/CHMP/689575/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Apexxnar

pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed)

On 16 December 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 Apexxnar, intended for prophylaxis against pneumococcal pneumonia and associated invasive disease. The applicant for this medicinal product is Pfizer Europe MA EEIG.

Apexxnar will be available as a suspension for injection. The active substance of Apexxnar (ATC code: J07AL02) is pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed), which elicits an immune response to all 20 serotypes contained in the product.

The benefit of Apexxnar is 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:

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.

Apexxnar should be used 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

