25 January 2024
EMA/CHMP/33149/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Prevenar 20 (previously Apexxnar)

pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed)

On 25 January 2024, 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 Prevenar 20. The marketing authorisation holder for this medicinal product is Pfizer Europe MA EEIG.

The CHMP adopted an extension to the existing indication for prophylaxis against pneumonia and acute otitis media caused by pneumococci and associated invasive disease, in infants, children and adolescents.

For information, the full indications for Prevenar 20 will be as follows[2]:

> Active immunisation for the prevention of invasive disease, pneumonia, and acute otitis media caused by *Streptococcus pneumoniae* in infants, children, and adolescents from 6 weeks to less than 18 years of age.
>
> 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~~Prevenar 20 should be used 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 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, removed text as strikethrough

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