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Prevenar 20[1] (*pneumococcal polysaccharide conjugate vaccine, 20-valent, adsorbed*)

An overview of Prevenar 20 and why it is authorised in the EU

What is Prevenar 20 and what is it used for?

Prevenar 20 is a vaccine to protect adults and children from 6 weeks of age against pneumonia (infection of the lungs) and invasive diseases (diseases that occur when a bacterium spreads through the body) caused by the bacterium *Streptococcus pneumoniae* (*S. pneumoniae*).

It is also used in children from 6 weeks to 17 years of age to protect against acute otitis media (ear infection).

Prevenar 20 contains parts from 20 different types of *S. pneumoniae*.

How is Prevenar 20 used?

Prevenar 20 can only be obtained with a prescription. Prevenar 20 is given as an injection into the muscle of the thigh in infants and the upper arm in older children and adults.

In adults, it is given as a single injection. In children and adolescents, the number of injections depends on their age and previous vaccination status.

For more information about using Prevenar 20, see the package leaflet or contact your healthcare provider.

How does Prevenar 20 work?

Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Prevenar 20 prepares the body to defend itself against invasive disease and pneumonia caused by *S. pneumoniae*.

Prevenar 20 contains small amounts of polysaccharides (a type of sugar) extracted from the 'capsule' that surrounds the *S. pneumoniae* bacterium. These polysaccharides have been purified, then conjugated (attached) to a carrier protein that helps the immune system to recognise them and respond in an enhanced manner. The vaccine is also adsorbed (fixed) onto an aluminium adjuvant (a substance to help strengthen the immune response to the vaccine). Prevenar 20 contains the

[1] Previously known as Apexxnar

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polysaccharides from 20 different types of *S. pneumoniae* that can cause invasive disease and pneumonia.

When a person is given Prevenar 20, the immune system recognises the polysaccharides in the vaccine as 'foreign' and makes antibodies against them. The immune system will then be able to produce antibodies more quickly when it comes into contact with the bacteria that have those polysaccharides on their capsules. This helps to protect against the disease.

What benefits of Prevenar 20 have been shown in studies?

Studies in adults

In 2 main studies, Prevenar 20 was shown to trigger immune responses that were comparable to those triggered by two other authorised pneumococcal vaccines (Prevenar 13, a vaccine that protects against 13 types of *S. pneumoniae;* Pneumovax 23, a vaccine that protects against 23 types of *S. pneumoniae*). Between them, Prevenar 13 and Pneumovax 23 cover the 20 types of *S. pneumoniae* (serotypes) targeted by Prevenar 20. Prevenar 20 was considered to be protective against pneumococcal disease based on the known effectiveness of Prevenar 13 and Pneumovax 23.

In one study conducted in around 3,000 people from 60 years of age, participants received either Prevenar 20, or Prevenar 13 followed one month later by Pneumovax 23. One month after each vaccination, the levels of antibodies across the 2 groups were comparable for all but one of the serotypes included in Prevenar 20. It was noted that although comparable, the antibody levels with Prevenar 20 were lower than with Prevenar 13 for most of the serotypes included in both vaccines.

This study also included around 900 people aged between 18 and 59 years who received either Prevenar 20 or Prevenar 13. In the Prevenar 20 group, the antibody levels against the 20 different serotypes were comparable to those seen in people aged 60 to 64 years who received Prevenar 20.

A second study tested Prevenar 20 in 875 participants who were at least 65 years of age and had all received a pneumococcal vaccine before (Prevenar 13 only, Pneumovax 23 only or Prevenar 13 followed by Pneumovax 23). In this study Prevenar 20 triggered immune responses against all serotypes and in all groups, but the immune responses differed considerably between the three different vaccine groups. Overall, the increase in antibodies after vaccination with Prevenar 20 was greater in people who had previously only received Prevenar 13 compared with those who had received Pneumovax 23 or Prevenar 13 followed by Pneumovax 23.

Studies in children

Two main studies looked at the immune response (as measured by the level of antibodies) triggered by Prevenar 20 compared with the response triggered by Prevenar 13 in a total of about 3,200 infants.

The results showed that Prevenar 20 triggered increased antibody levels against all 20 serotypes targeted by the vaccine; however, for some serotypes the antibody levels observed were lower with Prevenar 20 than with Prevenar 13.

When Prevenar 20 was given as a 4-dose regimen, the immune response was more similar to that seen with Prevenar 13 than when it was given as a 3-dose regimen. Therefore, only the 4-dose regimen has been approved for routine childhood immunisation.

What are the risks associated with Prevenar 20?

For the full list of side effects and restrictions with Prevenar 20, see the package leaflet.

In adults, the most common side effects with Prevenar 20 (which may affect more than 1 in 10 people) include pain at the injection site (which may limit arm movement), muscle pain, tiredness, headache, decreased appetite and joint pain.

In children and adolescents, very common side effects with Prevenar 20 (which may affect more than 1 in 10 people) include decreased appetite, irritability, pain, redness and swelling at the injection site, irritability, drowsiness or increased sleep, and restless or decreased sleep. Headache, muscle pain and tiredness are also very common in children above 5 years and adolescents. Fever is very common in children under 5 years of age.

These side effects were usually mild or moderate in intensity and resolved within a few days after vaccination.

Prevenar 20 must not be used in people who are hypersensitive (allergic) to diphtheria toxoid (a weakened toxin from the bacterium that causes diphtheria), to the active substances or to any of the other ingredients.

Why is Prevenar 20 authorised in the EU?

Prevenar 20 was found to trigger an immune response against all 20 serotypes contained in the vaccine; it is therefore expected to protect against pneumococcal disease. However, considering that for some serotypes the antibody levels observed were lower with Prevenar 20 than with the comparator vaccines, data on effectiveness are required to confirm the benefits of Prevenar 20. The side effects of Prevenar 20 are usually mild or moderate in intensity and similar to those seen with other pneumococcal vaccines.

The European Medicines Agency therefore decided that Prevenar 20's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Prevenar 20?

The company that markets Prevenar 20 is required to provide the results from three studies on the long-term effectiveness of Prevenar 20.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Prevenar 20 have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Prevenar 20 are continuously monitored. Suspected side effects reported with Prevenar 20 are carefully evaluated and any necessary action taken to protect patients.

Other information about Prevenar 20

Prevenar 20 received a marketing authorisation valid throughout the EU 14 February 2022.

Further information on Prevenar 20 can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/prevenar-20.

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