Apexxnar (pneumococcal polysaccharide conjugate vaccine, 20-valent, adsorbed)
An overview of Apexxnar and why it is authorised in the EU

What is Apexxnar and what is it used for?
Apexxnar is a vaccine to protect adults 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).

Apexxnar contains parts from 20 different types of S. pneumoniae.

How is Apexxnar used?
Apexxnar can only be obtained with a prescription.

Apexxnar is available as a suspension for injection. It is given as a single injection into the muscle of the upper arm.

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

How does Apexxnar work?
Vaccines work by ‘teaching’ the immune system (the body’s natural defences) how to defend itself against a disease. Apexxnar prepares the body to defend itself against invasive disease and pneumonia caused by S. pneumoniae.

Apexxnar 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). Apexxnar contains the polysaccharides from 20 different types of S. pneumoniae that can cause invasive disease and pneumonia.

When a person is given Apexxnar, 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 Apexxnar have been shown in studies?**

In 2 main studies, Apexxnar 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 Apexxnar. Apexxnar 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 Apexxnar, 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 Apexxnar. It was noted that although comparable, the antibody levels with Apexxnar 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 Apexxnar or Prevenar 13. In the Apexxnar group, the antibody levels against the 20 different serotypes were comparable to those seen in people aged 60 to 64 years who received Apexxnar.

A second study tested Apexxnar 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 Apexxnar 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 Apexxnar 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.

**What are the risks associated with Apexxnar?**

The most common side effects with Apexxnar (which may affect more than 1 in 10 people) are pain at the injection site, muscle pain, tiredness, headache, and joint pain. These were usually mild or moderate in intensity and resolved within a few days after vaccination.

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

For the full list of side effects and restrictions of Apexxnar, see the package leaflet.

**Why is Apexxnar authorised in the EU?**

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

The European Medicines Agency therefore decided that Apexxnar’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 Apexxnar?

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

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

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

Other information about Apexxnar

Apexxnar received a marketing authorisation valid throughout the EU on 14 February 2022.

Further information on Apexxnar can be found on the Agency’s website:

This overview was last updated in 02-2022.