



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Vaxneuvance (*pneumococcal polysaccharide conjugate vaccine, 15-valent, adsorbed*)

An overview of Vaxneuvance and why it is authorised in the EU

What is Vaxneuvance and what is it used for?

Vaxneuvance is a vaccine used to protect against three types of infections caused by the bacterium *Streptococcus pneumoniae* (*S. pneumoniae*):

- acute otitis media (ear infection), in children aged from 6 weeks to less than 18 years
- pneumonia (infection of the lungs), in adults and children from 6 weeks of age;
- invasive disease in adults and children from 6 weeks of age. (Invasive disease occurs when the bacterium spreads through the body, causing conditions such as septicaemia (blood infection) and meningitis (infection of the membranes around the brain and spine)).

Vaxneuvance contains parts from 15 different types of the *S. pneumoniae* bacterium. It also contains an adjuvant, a substance containing aluminium, to stimulate a better immune response.

How is Vaxneuvance used?

Vaxneuvance is given as injections in the muscle of the thigh in infants and the upper arm in older children and adults. The number of doses for children depends on their age and previous vaccination status, and should be based on official recommendations. People from 18 years of age require only one dose.

The vaccine can only be obtained with a prescription. For more information about using Vaxneuvance, see the package leaflet or contact your healthcare provider.

How does Vaxneuvance work?

Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. When a person is given the vaccine, the immune system recognises the parts of the bacterium contained in the vaccine as 'foreign' and makes antibodies against them. The immune system will then be able to produce antibodies more quickly when it is exposed to the bacterium again. This helps to protect against the disease.

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Vaxneuvance 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 to help the immune system recognise them. The vaccine is also 'adsorbed' (fixed) onto an aluminium compound to enhance the immune response.

Vaxneuvance contains the polysaccharides from 15 different types of *S. pneumoniae* (serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F).

What benefits of Vaxneuvance have been shown in studies?

The ability of Vaxneuvance to produce antibodies that can protect against *S. pneumoniae* infection in adults was shown in two main studies comparing the immune response measured 30 days after a single dose of Vaxneuvance with that caused by a single dose of a similar vaccine authorised in the EU (Prevenar 13) that contains 13 of the 15 different types of the *S. pneumoniae* bacterium contained in Vaxneuvance.

In the first study, involving 1,205 adults aged 50 and above, 52% to 81% of the 602 participants who were given Vaxneuvance had at least four times more antibodies against the 15 different types of *S. pneumoniae* than before vaccination. This response was comparable to that seen in the 600 participants who were given Prevenar 13.

The second study involved 1,515 adults aged 18 to 49 years (including individuals at increased risk of pneumococcal disease). Of the 1,133 participants who were given Vaxneuvance, 51.5% to 87.5% had at least four times more antibodies for the 15 different types than before vaccination. This immune response was comparable to that seen in the 379 patients who were given Prevenar 13.

In children, the ability of Vaxneuvance to trigger the production of antibodies was assessed in two main studies involving 2,904 healthy infants 6 weeks of age and older. In these studies, Vaxneuvance was as effective as Prevenar 13 at triggering antibody production for the 13 shared serotypes .

What are the risks associated with Vaxneuvance?

The most common side effects with Vaxneuvance in children aged 6 weeks to less than 2 years of age (which may affect more than 1 in 10 people) are irritability, sleepiness, reduced appetite, fever as well as reddening, hardening, swelling and pain at the site of injection.

The most common side effects in adults and children aged 2 years and above are tiredness, muscle pain, fever and headache, as well as pain, swelling and reddening of the skin at the site of injection.

Vaxneuvance must not be used in people who are hypersensitive (allergic) to diphtheria toxoid (a weakened toxin from the bacterium that causes diphtheria).

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

Why is Vaxneuvance authorised in the EU?

Vaxneuvance was shown to cause an immune response to different types of *S. pneumoniae*. This reaction is comparable to that caused by another authorised pneumococcal conjugate vaccine. It is therefore reasonable to conclude that Vaxneuvance can provide similar protection. Vaxneuvance also contains two types of *S.pneumoniae* not contained in the other vaccine. In addition, its most common side effects are mild and manageable. Therefore, the European Medicines Agency decided that Vaxneuvance'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 Vaxneuvance?

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

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

Other information about Vaxneuvance

Vaxneuvance received a marketing authorisation valid throughout the EU on 13 December 2021.

Further information on Vaxneuvance can be found on the Agency's website:

ema.europa.eu/medicines/human/EPAR/Vaxneuvance.

This overview was last updated in 11-2022.