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Capvaxive (*Pneumococcal polysaccharide conjugate vaccine (21-valent)*)

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

What is Capvaxive and what is it used for?

Capvaxive is a vaccine to protect adults against pneumonia (infection of the lungs) and invasive diseases caused by the bacterium *Streptococcus pneumoniae (S. pneumoniae*).

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).

Capvaxive contains parts from 21 different types of *S. pneumoniae*.

How is Capvaxive used?

Capvaxive can only be obtained with a prescription. The vaccine is given as a single injection into the muscle, preferably of the upper arm.

The vaccine should be used according to official recommendations issued at national level by public health bodies.

For more information about using Capvaxive, see the package leaflet or contact your doctor or pharmacist.

How does Capvaxive 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. This helps to protect against the disease.

Capvaxive contains small amounts of polysaccharides (a type of sugar) extracted from the 'capsule' that surrounds the *S. pneumoniae* bacterium. These polysaccharides have been purified and then 'conjugated' (attached) to a carrier protein to help the immune system recognise them.

Capvaxive contains the polysaccharides from 21 different types of *S. pneumoniae* (serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, deOAc15B, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F and 35B).

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What benefits of Capvaxive have been shown in studies?

Two main studies involving over 4,000 adults showed that Capvaxive is effective at triggering the production of antibodies targeting the 21 different types of *S. pneumoniae.* These studies compared the level of antibodies triggered by Capvaxive to those generated by two authorised pneumococcal vaccines 30 days after vaccination. These included Prevenar 20, which contains 10 of the 21 *S. pneumoniae* types in Capvaxive, and Pneumovax 23, which contains 12 of the 21 *S. pneumoniae* types in Capvaxive.

In the first study, among adults aged 50 years and older, people given Capvaxive produced similar levels of antibodies as those given Prevenar 20 for the 10 types of *S. pneumoniae* polysaccharides they have in common. Adults aged 50 years and older who were given Capvaxive also produced more antibodies against 10 of the other 11 types of polysaccharides that are not in Prevenar 20. Further data showed that antibody levels triggered by Capvaxive for all 21 polysaccharides in adults aged 18 to 49 years was comparable to those in adults aged 50 to 64 years.

In the second study, among adults aged 50 and older, people given Capvaxive produced similar levels of antibodies as those given Pneumovax 23 for the 12 types of *S. pneumoniae* polysaccharides they have in common. The study also showed that Capvaxive was more effective than Pneumovax 23 for the 9 other polysaccharides.

What are the risks associated with Capvaxive?

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

The most common side effects with Capvaxive (which may affect more than 1 in 10 people) include pain at the injection site, tiredness, headache and myalgia (muscle pain). Most side effects with Capvaxive are usually mild or moderate and get better within three days after vaccination.

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

Why is Capvaxive authorised in the EU?

Capvaxive triggered a strong immune response against 21 types of *S. pneumoniae*, as well as one additional, related type, as shown by the production of antibodies that protect against pneumococcal disease. Capvaxive is expected to provide a broader protection against different types of *S. pneumoniae*. making the vaccine particularly valuable in areas where there is a risk of contracting infections by *S. pneumoniae* types, not covered by existing vaccines. The safety profile of Capvaxive is comparable to that of other pneumococcal vaccines, with most side effects being mild or moderate and resolving a few days after vaccination.

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

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

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

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

Other information about Capvaxive

Capvaxive received a marketing authorisation valid throughout the EU on 24 March 2025.

Further information on Capvaxive can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/capvaxive

This overview was last updated in 03-2025.