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EPAR summary for the public

Prevenar

Pneumococcal saccharide conjugated vaccine, adsorbed

This is a summary of the European public assessment report (EPAR) for Prevenar. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Prevenar.

What is Prevenar?

Prevenar is a vaccine. It is a suspension for injection that contains parts of the bacterium *Streptococcus pneumoniae* (*S. pneumoniae*).

What is Prevenar used for?

Prevenar is used to vaccinate infants and children aged between two months and five years against diseases caused by *S. pneumoniae*. These include sepsis (blood infection), meningitis (infection of the membranes that surround the brain and spine), pneumonia (infection of the lungs), otitis media (infection of the middle ear) and bacteraemia (bacteria detected in the blood).

The medicine can only be obtained with a prescription.

How is Prevenar used?

The vaccination schedule to be used depends on the age of the child and should be based on official recommendations.

- Infants aged between two and six months need three doses. The first dose is usually given at two months of age with an interval of at least one month between doses. A fourth dose (booster) is recommended in the second year of life. Alternatively, when Prevenar is given as part of a 'universal infant immunisation programme' (when all infants in an area are vaccinated

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at around the same time), two doses can be given with an interval of at least two months, followed by a booster at 11 to 15 months of age.

- Infants aged between seven and 11 months need two doses, with an interval of at least one month between doses. A third dose is recommended in the second year of life.
- Children aged between 12 and 23 months need two doses, with an interval of at least two months between doses.
- Children aged between 24 months and five years need one single dose.

The vaccine is given by injection into the thigh muscle in infants, or into the upper arm muscle in young children.

How does Prevenar 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 bacterium contained in the vaccine as 'foreign' and makes antibodies against it. 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.

Prevenar 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 to help them be better recognised by the immune system. The vaccine is also 'adsorbed' (fixed) onto an aluminium compound to stimulate a better response.

Prevenar contains the polysaccharides from different types of *S. pneumoniae* (serotypes 4, 6B, 9V, 14, 18C, 19F and 23F). In Europe, it is estimated that these are responsible for about 54% to 84% of invasive infections (infections that have spread into the body) in infants and children under the age of two years, and for about 62% to 83% of invasive infections in children aged between two and five years.

How has Prevenar been studied?

The effectiveness of Prevenar in the prevention of *S. pneumoniae* invasive disease has been studied in almost 38,000 infants. Half of the infants received Prevenar, and the remainder received another vaccine that is not active against *S. pneumoniae*. Prevenar was given at two, four, six and 12 to 15 months of age. The study measured the number of children who developed an *S. pneumoniae* invasive disease during the 3.5 years of the study.

Additional studies looked at the effectiveness and safety of Prevenar in older infants and children, and at the development of antibodies in infants after the two-dose immunisation schedule followed by a booster injection.

What benefit has Prevenar shown during the studies?

Prevenar was effective in preventing *S. pneumoniae* invasive disease. During the main study, 49 cases of infection due to the serotypes 4, 6B, 9V, 14, 18C, 19F and 23F of *S. pneumoniae* were seen among the infants who received the control vaccine, compared with three cases among the infants vaccinated with Prevenar.

The additional studies showed that Prevenar was safe and effective in children up to the age of five years. In infants, the two-dose immunisation schedule led to the development of antibodies against

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S. pneumoniae, but to a lower level than the three-dose schedule. However, the CHMP concluded that this is unlikely to lead to a difference in the rate of protection against infection with *S. pneumoniae* following a booster injection, when Prevenar is used as part of a routine immunisation programme in which most infants are vaccinated.

What is the risk associated with Prevenar?

The most common side effects with Prevenar (seen in more than 1 patient in 10) are vomiting, diarrhoea, loss of appetite, reactions at the site of the injection (redness, hardening, swelling or pain), fever, irritability, drowsiness and restless sleep. For the full list of all side effects reported with Prevenar, see the package leaflet.

Prevenar should not be used in children who may be hypersensitive (allergic) to the *Streptococcus* vaccine, to any of the other ingredients or to the diphtheria toxoid (a weakened toxin from the bacterium that causes diphtheria). Vaccination should be postponed in children with a severe infection and high fever.

Why has Prevenar been approved?

The CHMP decided that Prevenar's benefits are greater than its risks and recommended that Prevenar be given marketing authorisation.

Other information about Prevenar

The European Commission granted a marketing authorisation valid throughout the European Union for Prevenar to Wyeth Lederle Vaccines S.A. on 2 February 2001. The marketing authorisation is valid for an unlimited period.

The full EPAR for Prevenar can be found on the Agency's website ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Prevenar, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

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