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Vaxneuvance® (active substance: pneumococcal polysaccharide conjugate vaccine (15-valent, adsorbed))

Indication extension in Switzerland: 9 January 2024

Vaccine for active immunisation for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* in infants and children (6 weeks to 5 years of age)

About the medicinal product

The active ingredients contained in the medicinal product Vaxneuvance are polysaccharides of *Streptococcus pneumoniae* serotypes 1 / 3 / 4 / 5 / 6A / 6B / 7F / 9V / 14 / 18C / 19A / 19F / 22F / 23F / 33F conjugated with the Corynebacterium diphtheriae CRM_{197} protein.

Vaxneuvance is a pneumococcal vaccine. It is used for active immunisation[1] for the prevention of invasive disease (for example meningitis), pneumonia and acute otitis media, caused by *Streptococcus pneumoniae* (pneumococci).

Vaxneuvance was authorised on 14 February 2023 for individuals aged 65 and older. With this indication extension, Vaxneuvance is now also authorised for infants and children aged between 6 weeks and 5 years.

The frequency of invasive pneumococcal diseases is highest among persons over the age of 65, children under 2 or 5 years, and in persons with certain chronic illnesses.

Despite previously authorised pneumococcal vaccines, the annual incidence[2] of an invasive pneumococcal disease in Switzerland is approximately 10 in 100,000 individuals.

Mode of action

Vaccines such as Vaxneuvance protect against infectious diseases by inducing the immune system to produce more antibodies or certain immune cells. The immune system

[1] Active immunisation refers to a process in which a person's immune system is stimulated to mount an immune response to a particular pathogen.

2 Incidence refers to the number of new cases of a certain disease that develop during a specific time period.

recognises parts of the bacterium contained in Vaxneuvance as foreign and creates antibodies against them. When exposed to the bacterium again, the immune system can then produce antibodies more quickly.

Vaxneuvance contains polysaccharides (special sugars) from the capsule of the pneumococcal bacterium (*Streptococcus pneumoniae*). There are more than 90 different types (serotypes) of this bacterium. Vaxneuvance uses the polysaccharides from 15 serotypes. In order to make these polysaccharides more visible to the immune system, and thereby trigger a stronger reaction from the immune system, they are bound (conjugated) to a protein from a different bacterium (*Corynebacterium diphtheriae*).

Unlike the pneumococcal vaccine Prevenar 13 (PCV13) already authorised in Switzerland and containing 13 serotypes, Vaxneuvance also uses an additional 2 serotypes (22F and 33F).

Administration

Vaxneuvance is a prescription-only medicine.

Vaxneuvance is available as a pre-filled syringe containing a dose of 0.5 mL. Vaxneuvance is administered to infants in the thigh muscle and injected into the upper arm muscle of children and adults.

Infants and children are normally given 3 doses of a pneumococcal vaccine.

Individuals over 65 years of age receive a single dose.

Efficacy

The immunogenicity study (V114-025) shows that, compared to PCV13, the vaccine that is already on the market, Vaxneuvance triggers a comparable immune response (formation of antibodies) to 13 shared serotypes. Other studies with PCV13 demonstrated that this immune response is associated with disease prevention.

The clinical efficacy, i.e. the protective effect, of this immune response to pneumococcal disease in infants and children between 6 weeks and 5 years can therefore also be assumed to apply to Vaxneuvance. The 2 additional serotypes (22F and 33F) likewise resulted in a measurable immune response. The clinical efficacy of these 2 additional serotypes has not been investigated.

Certain *Streptococcus pneumoniae* serotypes are not contained in Vaxneuvance. No protection against illnesses caused by these serotypes is afforded by Vaxneuvance.

Precautions, undesirable effects, & risks

Vaxneuvance must not be used in those who are hypersensitive to one of the active substances or any of the excipients.

The most common undesirable effects differ according to age group. The principal effects in infants (6 weeks to 23 months) are fever (75%), irritability (75%), and somnolence (55%). In children (2 to 5 years), undesirable effects are pain (38%), swelling (21%), or rash at the injection site (21%). Older individuals experience pain at the injection site (63%), fatigue (20%), and muscle pain (20%).

All precautions, risks, and other possible undesirable effects are listed in the Information for healthcare professionals.

Why the medicinal product has been authorised

The pivotal study verified the comparable immune responses produced by Vaxneuvance and PCV13 in infants and children in the age group of 6 weeks to 5 years. The clinical efficacy (prevention of disease caused by the pneumococcal bacterium), which is confirmed by the existing study data for PCV13 in this age group, can therefore also be assumed to apply to Vaxneuvance.

Based on these findings, Swissmedic has approved the indication extension for the medicinal product Vaxneuvance for the age group described.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Vaxneuvance®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

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