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

First authorisation in Switzerland: 14 February 2023

Vaccine for active immunisation[1] to prevent invasive diseases and pneumonia caused by *Streptococcus pneumoniae*

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 used in persons aged 65 years and older for active immunisation[1] to prevent invasive diseases such as meningitis and pneumonia (inflammation of the lungs) caused by *Streptococcus pneumoniae* (pneumococci). 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. In Switzerland, approximately 80% of severe pneumococcal infections occur in persons aged 65 and over.

As at the time of Vaxneuvance's marketing authorisation, there is another pneumococcal conjugate vaccine available in Switzerland with different components than Vaxneuvance (see "Mode of action").

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 recognises parts of the bacterium contained in Vaxneuvance as foreign and create antibodies against them. When exposed to the

[1] Active immunisation refers to a process in which a person's immune system is induced to develop an immune response to a specific pathogen.

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

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. To make these polysaccharides more easily recognisable for the immune system, and thereby elicit a good immune response, they are attached to (conjugated with) a protein from another bacterium.

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.

It is available as a 0.5 mL pre-filled syringe. Vaxneuvance is normally injected once into the muscle of the upper arm.

No booster shot is needed.

Efficacy

The efficacy of Vaxneuvance is based on results from a study with 1,205 subjects over the age of 50 who had no prior history of pneumococcal infections or vaccines. This study compared the immune response (development of antibodies) of the study participants after receiving Vaxneuvance with the immune response after receiving PCV13. The study was carried out in 5 countries (USA, Canada, Japan, Spain, and Taiwan). The median[3] age was 66 years (range: 50 to 92 years); 69% of participants were aged 65 and over; 57% of participants were women and 87% had at least 1 pre-existing condition.

The study found that the immune response induced by Vaxneuvance was not inferior to that of PCV13 for the 13 common serotypes and was superior for the 2 additional serotypes (22F and 33F). The same result was found with a sub-group study of those 830 participants aged 65 or older.

Precautions, undesirable effects, & risks

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

The most commonly reported adverse reactions were injection site pain (63%), fatigue (20%), muscle pain (20%), headache (15%), and injection-site swelling (15%).

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

[3] Median: The value that lies exactly in the middle of a distribution of data is called the median or central value. Half of the data values are always less than the median, the other half are always greater.

Why the medicinal product has been authorised

In all studies performed with Vaxneuvance that were submitted for the marketing authorisation, a total of 5,630 subjects received Vaxneuvance. The pivotal study with 1,205 subjects demonstrated a similar immune response to that after vaccination with PCV13. For adults over the age of 65, another study with PCV13 (CAPiTA study) showed that this immune response is associated with a prevention of the diseases. Therefore, in adults over the age of 65 after being vaccinated with Vaxneuvance, sufficient protection from diseases caused by pneumococci can also be assumed.

No clinical data of this kind are available for adults under the age of 65. Therefore, the indication was restricted accordingly in terms of age.

Taking all the risks and precautions into account, and based on the available data, the benefits of Vaxneuvance outweigh the risks. Swissmedic has therefore authorised the medicinal product Vaxneuvance (a pneumococcal polysaccharide conjugate vaccine, 15-valent, adsorbed) for use in Switzerland.

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.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.