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Summary report on authorisation dated 29 November 2024

Prevenar 20® (active substance: Pneumococcal polysaccharide conjugate vaccine 20-valent, adsorbed)

Authorisation in Switzerland: 26 March 2024

Vaccine for active immunisation for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* in adults 65 years of age and older

About the medicinal product

The active ingredients contained in the medicinal product Prevenar 20 are polysaccharides of *Streptococcus pneumoniae* serotypes 1 / 3 / 4 / 5 / 6A / 6B / 7F / 8 / 9V / 10A / 11A /12F / 14 / 15B / 18C / 19A / 19F / 22F / 23F / 33F, conjugated to *Corynebacterium diphtheriae* CRM-197 protein.

Prevenar 20, a pneumococcal vaccine, is used in adults 65 years of age and older for active immunisation[1] to prevent invasive diseases (for example meningitis) and pneumonia (inflammation of the lungs) caused by *Streptococcus pneumoniae* (pneumococci).

In roughly 20 % of patients aged over 65 suffering from pneumonia due to pneumococci the disease has a fatal outcome.

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 Prevenar 20 protect against infectious diseases by stimulating the immune system to produce more antibodies or certain immune cells. The immune system recognises parts of the bacterium contained in Prevenar 20 as foreign and creates antibodies against them. When exposed to the bacterium again, the immune system can then produce antibodies more quickly.

[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.

Prevenar 20 contains polysaccharides (special sugars) from the capsule of the pneumococcal bacterium (*Streptococcus pneumoniae*). There are more than 90 different types (serotypes) of this bacterium. Prevenar 20 uses the polysaccharides from 20 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 already authorised in Switzerland and containing 13 serotypes, Prevenar 20 also uses an additional 7 serotypes (8 / 10A / 11A / 12F / 15F / 22F and 33F).

Administration

The vaccine Prevenar 20 is a prescription-only medicine.

Prevenar 20 is available as a pre-filled syringe containing a dose of 0.5 mL.

Prevenar 20 is administered to adults 65 years of age and older as single dose injected into a muscle, preferably the shoulder muscle.

Efficacy

The immunogenicity study (pivotal study 1007) showed that, compared to Prevenar 13, the vaccine that is already on the market, Prevenar 20 elicits a comparable immune response (formation of antibodies) to the 13 shared serotypes.

The immune response to the 7 serotypes additionally contained in Prevenar 20 was investigated in subsequent immunogenicity studies with participants aged 65 and older. The participants had previously been vaccinated with PPSV23 (unconjugated pneumococcal polysaccharide vaccine) or Prevenar 13. The studies showed that Prevenar 20 also elicited an immune response to the 7 additional serotypes in adults 65 years of age and older.

While no specific studies have investigated the clinical efficacy of Prevenar 20, the results of the CAPiTA study, which demonstrated clinical efficacy for Prevenar 13, can be applied to Prevenar 20.

Therefore, clinical efficacy, i.e. the protective effect of this immune response to pneumococcal disease, can also be assumed to apply to Prevenar 20. The 7 additional serotypes likewise resulted in a measurable immune response.

Certain *Streptococcus pneumoniae* serotypes are not contained in Prevenar 20. No protection against illnesses caused by these serotypes is afforded by Prevenar 20.

Precautions, undesirable effects, & risks

Prevenar 20 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 (affecting more than 1 in 10 users) are pain at the injection site (61 %), muscle pain (39 %), fatigue (30 %), headache (21 %), and joint pain (17 %).

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 confirmed that the immune response of Prevenar 20 is comparable with that of Prevenar 13 in adults 65 years of age and older. The clinical efficacy (prevention of disease caused by the pneumococcal bacterium), which is confirmed by the existing study data for Prevenar 13 in this age group, can therefore also be assumed to apply to Prevenar 20.

Based on these findings, and taking all the available data into account, the benefits of Prevenar 20 outweigh the risks. Swissmedic has therefore authorised the medicinal product Prevenar 20 for adults 65 years of age and older.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Prevenar 20®

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 Summary report on authorisation.

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