

Summary report on authorisation dated 6 March 2026

CAPVAXIVE[®] (active substance: Pneumococcal polysaccharide conjugate vaccine (21-valent))

Authorisation in Switzerland: 23 September 2025

Vaccine for active immunisation for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* in adults 18 years of age and older

About the medicinal product

The active substances contained in the medicinal product CAPVAXIVE are parts of 21 different types of *Streptococcus pneumoniae* (pneumococci) – serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, de-O-acetylated 15B, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, 35B – conjugated to Corynebacterium diphtheriae CRM197 protein.

CAPVAXIVE is a pneumococcal vaccine. It is used in adults 18 years of age and older for active immunisation¹ to prevent invasive dis-

eases (for example 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 over the age of 18 with certain chronic illnesses.

Despite pneumococcal vaccines having already been authorised, the annual incidence² of invasive pneumococcal disease in Switzerland is approximately 10 in 100,000 individuals.

Mode of action

Vaccines such as CAPVAXIVE 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

CAPVAXIVE 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.

CAPVAXIVE contains polysaccharides (special sugars) from the capsule of the pneumococcal bacterium (*Streptococcus pneumoniae*). There are more than 90 different types (serotypes) of this bacterium. The polysaccharides from 21 serotypes are used in CAPVAXIVE (serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, deOAc15B, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F and 35B). 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*).

CAPVAXIVE covers serotypes not contained in the pneumococcal vaccines already authorised in Switzerland.

Administration

The vaccine CAPVAXIVE is only available with a prescription.

CAPVAXIVE is available as a pre-filled syringe containing a 0.5 mL dose.

CAPVAXIVE is administered to adults 18 years of age and older as single dose injected into a muscle, preferably the shoulder muscle.

Efficacy

The pivotal studies (V116-P003, V116-P017) showed that, compared to the vaccines already authorised in Switzerland – Prevenar 20 and Pneumovax 23 – CAPVAXIVE elicits a comparable immune response (formation of antibodies) to the 10 and 12 shared serotypes, respectively, in adults 50 years of age and older. The 11 and 9 additional serotypes, respectively, likewise resulted in an acceptable immune response. Study V116-003 also showed that the immune response elicited by CAPVAXIVE in adults between 18 and 49

years of age was comparable to that in adults aged 50 to 64.

No specific studies have investigated the clinical efficacy of CAPVAXIVE, i.e. how effective the immune response is in protecting against pneumococcal disease.

The immune response data indicate that CAPVAXIVE protects against the serotypes contained in the vaccine in a way that prevents invasive diseases and pneumonia.

Precautions, undesirable effects, & risks

CAPVAXIVE may 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 patients) are pain,

redness and swelling at the injection site, headache, muscle pain and fatigue.

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 studies showed that CAPVAXIVE elicits a good immune response to the 21 serotypes contained in the vaccine. Immune response to the shared types was similar in adults to that of two existing authorised vaccines (Prevenar 20 and Pneumovax 23). The

study data show that the safety profile of CAPVAXIVE corresponds to that of the two authorised comparator vaccines against pneumococci.

CAPVAXIVE is expected to provide protection against the additional serotypes not

covered by the other pneumococcal vaccines.

Taking all the risks and precautions into account, and based on the available data, the

benefits of CAPVAXIVE outweigh the risks. Swissmedic has therefore authorised the medicinal product CAPVAXIVE for adults 18 years of age and older.

Further information on the medicinal product

Information for healthcare professionals: [Information for healthcare professionals CAPVAXIVE®](#)

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.

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.