

Summary report on authorisation dated 27 March 2026

Prevenar 20[®] (active substance: pneumococcal polysaccharide conjugate vaccine 20-valent, adsorbed)

Indication extension in Switzerland: 13 June 2025

Vaccine for active immunisation for the prevention of invasive disease, pneumonia and acute otitis media caused by *Streptococcus pneumoniae* in infants and children from 6 weeks to 5 years of age

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, was first authorised by Swissmedic on 26 March 2024 for use in adults 65 years of age and older for active immunisation¹ to prevent invasive diseases (for example blood poisoning) and pneumonia (inflammation of the lungs) caused by *Streptococcus pneumoniae* (pneumococci).

As a result of this indication extension, Prevenar 20 can be used for active immunisation for the prevention of invasive disease, pneumonia and acute otitis media (inflammation

of the middle ear) caused by *Streptococcus pneumoniae* in infants and children from 6 weeks to 5 years of age.

In deciding whether to authorise the indication extension for Prevenar 20, Swissmedic took into account the assessments of the European Medicines Agency (EMA) and the corresponding medicinal product information texts.

Since the assessment of the clinical data was based on the assessment reports of a foreign authority, the preconditions for a SwissPAR (Swiss Public Assessment Report) and a resulting Summary Report on authorisation are not met. Swissmedic refers to the authorisation of the foreign reference authority www.ema.europa.eu.

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.

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.

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.