swissmedic

Date: 2 February 2026
Swissmedic, Swiss Agency for Therapeutic Products

Swiss Public Assessment Report
Extension of therapeutic indication

Prevenar 20

International non-proprietary name: *Streptococcus pneumoniae* serotype 1 / 3 / 4 / 5 / 6A / 6B / 7F / 8 / 9V / 10A / 11A / 12F / 14 / 15B / 18C / 19A / 19F / 22F / 23F / 33F polysaccharide conjugated to *Corynebacterium diphteriae* CRM197 protein

Pharmaceutical form:	suspension for injection in pre-filled syringe
Dosage strength(s):	2.2 µg of each serotype / 0.5 mL
Route(s) of administration:	intramuscular
Marketing authorisation holder:	Pfizer AG
Marketing authorisation no.:	69222
Decision and decision date:	extension of therapeutic indication approved on 13 June 2025

Note:

This assessment report is as adopted by Swissmedic with all information of a commercially confidential nature deleted.

SwissPARs are final documents that provide information on submissions at a particular point in time. They are not updated after publication.

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1 Terms, Definitions, Abbreviations

ADA	Anti-drug antibody
ADME	Absorption, distribution, metabolism, elimination
AE	Adverse event
ALT	Alanine aminotransferase
AOM	Acute otitis media
API	Active pharmaceutical ingredient
AST	Aspartate aminotransferase
ATC	Anatomical Therapeutic Chemical Classification System
AUC	Area under the plasma concentration-time curve
$AUC_{0\text{-}24h}$	Area under the plasma concentration-time curve for the 24-hour dosing interval
BLA	Biologics License Application
CI	Confidence interval
C_{max}	Maximum observed plasma/serum concentration of drug
CYP	Cytochrome P450
DDI	Drug-drug interaction
EMA	European Medicines Agency
ERA	Environmental risk assessment
FDA	Food and Drug Administration (USA)
GI	Gastrointestinal
GLP	Good Laboratory Practice
HPLC	High-performance liquid chromatography
IC/EC_{50}	Half-maximal inhibitory/effective concentration
ICH	International Council for Harmonisation
Ig	Immunoglobulin
INN	International non-proprietary name
IPD	Invasive pneumococcal disease
ITT	Intention-to-treat
LoQ	List of Questions
MAH	Marketing authorisation holder
Max	Maximum
Min	Minimum
MRHD	Maximum recommended human dose
N/A	Not applicable
NO(A)EL	No observed (adverse) effect level
PBPK	Physiology-based pharmacokinetics
PCV	Pneumococcal conjugate vaccine
PD	Pharmacodynamics
PIP	Paediatric investigation plan (EMA)
PK	Pharmacokinetics
PopPK	Population pharmacokinetics
PSP	Pediatric study plan (US FDA)
RMP	Risk management plan
SAE	Serious adverse event
STN	Submission tracking number (US FDA)
SwissPAR	Swiss Public Assessment Report
TEAE	Treatment-emergent adverse event
TPA	Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (SR 812.21)
TPO	Ordinance of 21 September 2018 on Therapeutic Products (SR 812.212.21)
WHO	World Health Organization

2 Background information on the procedure

2.1 Applicant's request(s) and information regarding procedure

Extension(s) of the therapeutic indication(s)
The applicant requested the addition of a new therapeutic indication or modification of an approved indication in accordance with Article 23 TPO.

2.2 Indication and dosage

2.2.1 Requested indication

Active immunisation for the prevention of invasive disease, pneumonia and otitis media caused by *Streptococcus pneumoniae* (serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, 33F) in infants and children from 6 weeks to 5 years of age.

2.2.2 Approved indication

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.

2.2.3 Requested dosage

Summary of the requested standard dosage:

Two vaccination schemes are proposed for infants and toddlers from 6 weeks to 15 months of age:

3 doses of 0.5ml i.m. (i.e. 2-dose primary series followed by a booster dose)	1st dose from 2 months of age; the 2nd dose to be given 2 months later. The 3rd (booster) dose to be given at 11-15 months of age. The 1st dose may also be given at 6 weeks of age.
4 doses of 0.5ml i.m. (i.e. 3-dose primary series followed by a booster dose)	1st dose from 2 months of age, followed by two doses at least 4 weeks apart. It is recommended that the 4th dose (booster) be given at 11-15 months of age. The 1st dose may also be given at 6 weeks of age.

The 4-dose schema described in the table above is proposed for neonates born before the 37th week of pregnancy.

Further dosing instructions:

Infants and children aged up to 15 months who have previously been vaccinated with another pneumococcal vaccine	Vaccination may continue using Prevenar 20 at any point of the vaccination series
Catch-up vaccination for infants and children aged between 7 months and 5 years	• Infants aged 7 up to 12 months with no previous vaccination: 2 doses of 0.5ml i.m. at least 4 weeks apart. A 3rd dose in the 2nd year is recommended • Children aged 12 up to 24 months with no previous vaccination: 2 doses of 0.5ml i.m. at least 8 weeks apart

	• Children aged 2 up to 5 years: single dose 0.5ml i.m. • Children from 12 months up to 5 years previously vaccinated with a pneumococcal conjugate vaccine: 1 dose of 0.5ml i.m. at least 8 weeks after the previous dose.

The applicant withdrew the initially requested 3-dose schedule for infants 6 weeks to 6 months of age consisting of 2 primary doses and one booster dose.

2.2.4 Approved dosage

(See appendix)

2.3 Regulatory history (milestones)

Application	30 May 2024
Formal control completed	27 June 2024
List of Questions (LoQ)	24 October 2024
Response to LoQ	20 December 2024
Preliminary decision	28 February 2025
Response to preliminary decision	29 April 2025
Informal exchange labelling	3 June 2025
Response to informal exchange labelling	10 June 2025
Final decision	13 June 2025
Decision	approval

3 Medical context

Streptococcus pneumoniae, also known as pneumococcus, can cause a variety of infections, including otitis media (AOM), pneumonia, and invasive pneumococcal disease (IPD) such as septicaemia, meningitis or bacteraemic pneumonia.
Rates of IPD are highest in children under 5 and adults over 65 years of age and (especially) in individuals with certain chronic health conditions, including chronic pulmonary/heart/lung disease, diabetes, splenic dysfunction, immunosuppression/immunodeficiency, cerebral spinal fluid leak, Cochlear implant, smoking, or alcoholism.

Pneumococcal infections are treated with antibiotics and the choice of antibiotic should reflect local resistance patterns and national treatment guidelines.

Childhood immunisation against *S. pneumoniae* is the most effective public health measure for preventing IPD caused by the vaccine-targeted serotypes, both among vaccine recipients (direct effect) and among unvaccinated populations (indirect 'herd' effect), as children are the main carriers. However, the replacement of the serotypes with non-vaccine serotypes is a contributor to the stable or minimally changing overall disease rates in several regions.
Pneumococcal conjugate vaccines (PCVs) include pneumococcal polysaccharides conjugated to a carrier protein (CRM_{197}) and aluminium phosphate adjuvant. They induce a T-cell-dependent immune response, which is especially relevant for infants and toddlers up to 2 years of age, as the B-cell response in this age group is not fully matured. Additionally, a T-cell-dependent immune response is of importance for inducing long-lasting immune memory.

In Switzerland, the Federal Commission for Vaccination recommends pneumococcal vaccination for children under 5 years of age and for older children and adults with health conditions entailing a high risk of invasive pneumococcal disease, and healthy adults aged 65 and over. Primary immunisation in infancy is recommended, with a 2+1 schedule at the age of 2, 4 and 12 months.

Prevenar 20 includes 7 additional serotypes compared to the 13-valent PCV (PCV13) and 5 additional serotypes compared to the 15-valent PCV (PCV15).
Based on European data from 2022, 3.8% of IPD cases in children under 5 years old with serotype information were caused by a PCV15/non-PCV13 serotype, 17.2% by a PCV20/non-PCV15 serotype, and 33.1% by a serotype not included in any currently available PCV.

4 Nonclinical aspects

Additional nonclinical studies were not conducted to support the requested extension for Prevenar 20 for vaccination of newborns and children aged 6 weeks to 5 years. This is acceptable since there are no relevant changes with regard to dose and method of administration. The more frequent administration to children was assessed in the clinical setting. An ERA is not warranted for vaccines. From the nonclinical standpoint, there are no objections to the approval of the requested extension.

5 Clinical aspects

Swissmedic has only assessed parts of the primary data submitted with this application. As regards the remaining data on clinical immunogenicity and safety in infants and children from 6 weeks to 5 years of age, Swissmedic relies for its decision on the assessment of the EMA.
This SwissPAR relates to the publicly available assessment report for Prevenar 20 published on 25 January 2024, Procedure No. EMA/66027/2024. In addition, account was taken of FDA BLA Clinical Review Memorandum STN: 125731/189.

6 Risk management plan summary

The RMP summaries contain information on the medicinal products′ safety profiles and explain the measures that are taken to further investigate and monitor the risks, as well as to prevent or minimise them.
The RMP summaries are published separately on the Swissmedic website. It is the responsibility of the marketing authorisation holder to ensure that the content of the published RMP summaries is accurate and correct. As the RMPs are international documents, their summaries might differ from the content in the Information for healthcare professionals / product information approved and published in Switzerland, e.g. by mentioning risks that occur in populations or indications not included in the Swiss authorisations.

7 Appendix

Approved Information for healthcare professionals

Please be aware that the following version of the Information for healthcare professionals for Prevenar 20 was approved with the submission described in the SwissPAR. This Information for healthcare professionals may have been updated since the SwissPAR was published.

Please note that the valid and relevant reference document for the effective and safe use of medicinal products in Switzerland is the Information for healthcare professionals currently authorised by Swissmedic (see www.swissmedicinfo.ch).

Note:
The following Information for healthcare professionals has been translated by the MAH. It is the responsibility of the authorisation holder to ensure the translation is correct. The only binding and legally valid text is the Information for healthcare professionals approved in one of the official Swiss languages.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected new or serious adverse reactions. See the «Undesirable effects» section for advice on the reporting of adverse reactions.

Prevenar 20®

Composition

Active substances

Polysaccharida streptococci pneumoniae (serotype 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, 33F) conjugatum cum proteinum corynebacteriae diphteriae CRM_{197}.

Adjuvant

Aluminii phosphas.

Excipients

Natrii chloridum (corresp. 1.73 mg sodium), acidum succinicum, polysorbatum 80, aqua ad iniectabilia.

Pharmaceutical form and active substance quantity per unit

Suspension for i.m. injection in pre-filled syringe.

One dose (0.5 ml) contains 2.2 µg of each pneumococcal polysaccharide of the serotypes 1, 3, 4, 5, 6A, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, 33F as well as 4.4 µg of serotype 6B (in total 46.2 µg of polysaccharides) conjugated to CRM_{197} carrier protein (approximately 51 µg per dose) and adsorbed on aluminium phosphate (0.125 mg aluminium per dose).

The vaccine is a homogeneous white suspension.

Indications/Uses

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

Active immunisation for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* in individuals 65 years of age and older.

Prevenar 20 does not protect against diseases caused by S. *pneumoniae* serotypes not contained in the vaccine.

For information on protection against specific pneumococcal serotypes, see «Warnings and Precautions» and «Properties/Effects».

Prevenar 20 should be used in accordance with official recommendations.

Dosage/Administration

Usual dosage

Infants and children 6 weeks to 5 years of age

It is recommended that infants who receive a first dose of Prevenar 20 complete the vaccination course with Prevenar 20.

Infants aged 6 weeks to 6 months

The recommended immunisation series consists of 4 doses, each of 0.5 ml (3-dose primary series followed by a booster dose).

The primary infant series consists of 3 doses, with the first dose usually given at the age of 2 months, the second dose at the age of four months and the third dose at the age of six months.

The first dose may be given as early as 6 weeks of age, with an interval of at least 4 weeks between doses.

The fourth (booster) dose is recommended between 11-15 months of age (see «Properties/Effects»).

No or only limited data are available for Prevenar 20 in preterm, older unvaccinated, or partially vaccinated infants and children (see «Warnings and precautions» and «Properties/Effects»).

The following dosing recommendations are predominantly based on experience with Prevenar 13.

Preterm infants (<37 weeks of gestation)

The recommended immunisation series for Prevenar 20 consists of 4 doses, each of 0.5 ml. The primary infant series consists of 3 doses, with the first dose usually given at the age of 2 months and with an interval of at least 4 weeks between doses. The first dose may be given as early as 6 weeks of age. The fourth (booster) dose is recommended between 11-15 months of age (see «Warnings and precautions» and «Properties/Effects»).

Catch-up vaccination schedules for unvaccinated infants and children 7 months to less than 5 years

Unvaccinated infants 7 to less than 12 months of age	3 doses	Two doses, each of 0.5 ml, with an interval of at least 4 weeks between doses. A third dose is recommended in the second year of life.
Unvaccinated children 12 to <24 months of age	2 doses	Two doses, each of 0.5 ml, with an interval of at least 8 weeks between doses.
Unvaccinated children 2 to <5 years of age	1 dose	One single dose of 0.5 ml.

Catch-up vaccination schedules for children 12 months to <5 years previously fully vaccinated with Prevenar 13

One single dose (0.5 ml) given on an individual basis according to official recommendations to elicit immune responses to the additional serotypes.

If Prevenar 13 was administered, at least 8 weeks should elapse before administering Prevenar 20 (see «Properties/Effects»).

Individuals 65 years of age and older

Prevenar 20 is to be administered as a single dose to individuals 65 years of age and older.

The need for revaccination with a subsequent dose of Prevenar 20 has not been investigated.

No data on sequential vaccination with other pneumococcal vaccines or a booster dose are available for Prevenar 20. Based on the clinical experience with Prevenar 13 (a pneumococcal conjugate vaccine consisting of 13 polysaccharide conjugates that are also in Prevenar 20), if the use of 23-valent pneumococcal polysaccharide vaccine (PPSV23) is considered appropriate, Prevenar 20 should be given first (see «Properties/Effects»).

Traceability

To ensure traceability of biotechnological medicinal products, it is recommended that the trade name and batch number should be documented for each treatment.

Special dosage instructions

There are no data with Prevenar 20 in special populations.

Children and adolescents

The safety and efficacy of Prevenar 20 in infants younger than 6 weeks of age have not been established. No data are available.

Mode of administration

For intramuscular use only.

The dose (0.5 ml) of Prevenar 20 should be given by intramuscular injection. The preferred sites are the anterolateral aspect of the thigh (vastus lateralis muscle) in infants or the deltoid muscle of the upper arm in children and adults. Prevenar 20 should be administered with care to avoid injection into or near nerves and blood vessels.

For instructions on the handling of the vaccine before administration, see section «Other Information», «Instructions for handling».

Contraindications

Hypersensitivity to the active substances, to any of the excipients mentioned in section «Composition», or to diphtheria toxoid.

Warnings and precautions

Do not inject Prevenar 20 intravascularly.

Hypersensitivity

As with all injectable vaccines, appropriate medical treatment and supervision must always be readily available in case of a rare anaphylactic reaction following the administration of the vaccine.

Concurrent illness

Vaccination should be postponed in individuals suffering from acute severe febrile illness. However, the presence of a minor infection, such as a cold, should not result in the deferral of vaccination.

Thrombocytopenia and coagulation disorders

The vaccine must be administered with caution to individuals with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration.

The risk of bleeding in patients with coagulation disorders needs to be carefully evaluated before intramuscular administration of any vaccine, and subcutaneous administration should be considered if the potential benefit clearly outweighs the risks.

Protection against pneumococcal disease

Prevenar 20 will only protect against *Streptococcus pneumoniae* serotypes included in the vaccine, see «Clinical efficacy», and will not protect against other microorganisms that cause invasive disease, pneumonia or otitis media. As with any vaccine, Prevenar 20 may not protect all individuals receiving the vaccine from pneumococcal disease.

Immunocompromised individuals

Safety and immunogenicity data on Prevenar 20 are not available for individuals in immunocompromised groups. Vaccination should be considered on an individual basis.

Based on experience with pneumococcal vaccines, some individuals with altered immunocompetence may have reduced immune responses to Prevenar 20.

Individuals with impaired immune response, whether due to the use of immunosuppressive therapy, a genetic defect, HIV infection, or other causes, may have reduced antibody response to active immunization. The clinical relevance of this is unknown.

Pediatric population

The potential risk of apnoea and the need for respiratory monitoring for 48-72 h should be considered when administering the primary immunisation series to very premature infants (born ≤28 weeks of gestation), and particularly for those with a previous history of respiratory immaturity. As the benefit of vaccination is high in this group of infants, vaccination should not be withheld or delayed.

Excipients of particular interest

This medicinal product contains less than 1 mmol sodium (23 mg) in each dose of vaccine (0.5 ml suspension for injection), i.e. it is almost «sodium-free».

Interactions

Different injectable vaccines should always be administered at different vaccination sites.

Do not mix Prevenar 20 with other vaccines/medicinal products in the same syringe.

Pediatric population

In clinical studies with infants and toddlers 6 weeks to less than 15 months of age, concomitant administration of Prevenar 20 with the following vaccine antigens, either as monovalent or combination vaccines, was investigated: diphtheria, tetanus, acellular pertussis, *Haemophilus influenzae* type b, inactivated poliomyelitis, hepatitis B, measles, mumps, rubella (MMR) and varicella vaccines. In clinical trials, rotavirus vaccines were permitted to be administered concomitantly with Prevenar 20 and no safety concerns were observed.

Individuals 65 years of age and older

Concomitant administration of Prevenar 20 with a seasonal influenza vaccine (QIV; surface antigen, inactivated, adjuvanted) was investigated in a study with adults aged 65 years and older. In subjects with underlying conditions associated with a high risk of developing life-threatening pneumococcal disease, consideration may be given to separating administrations of QIV and Prevenar 20 (e.g., by approximately 4 weeks). In a double-blind, randomised study (B7471004) in adults 65 years of age and older, the immune response was formally noninferior, however numerically lower titres were observed for all pneumococcal serotypes included in Prevenar 20 when given concomitantly with seasonal influenza vaccine (QIV, surface antigen, inactivated, adjuvanted) compared to when Prevenar 20 was given alone. The clinical relevance of this finding is unknown.

Concomitant administration of Prevenar 20 with COVID-19 mRNA vaccine (nucleoside modified) was investigated in a study with adults aged 65 years and older. Thereby, the immune response was comparable between participants receiving Prevenar 20 and saline placebo versus participants receiving Prevenar 20 and the Covid-19 mRNA vaccine (nucleoside modified).

There are no data on the concomitant administration of Prevenar 20 with other vaccines.

Pregnancy, lactation

Pregnancy

There are no data on the use of Prevenar 20 in pregnant women.

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity.

Administration of Prevenar 20 in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and foetus.

Lactation

It is unknown whether Prevenar 20 is excreted in human milk.

Fertility

No human data on the effect of Prevenar 20 on fertility are available. Animal studies do not indicate direct or indirect harmful effects with respect to female fertility (see «Preclinical data»).

Effects on ability to drive and use machines

Prevenar 20 has no or negligible influence on the ability to drive and use machines. However, some of the effects mentioned under section «Undesirable effects» may temporarily affect the ability to drive or use machines.

Undesirable effects

Summary of the safety profile

Pediatric population

The safety of Prevenar 20 was evaluated in 5987 participants 6 weeks to less than 18 years of age in four randomized, double-blind, active-controlled clinical trials and one single-arm clinical trial (one Phase 2 and four Phase 3); 3664 participants received at least 1 dose of Prevenar 20, and 2323 participants received Prevenar 13 (control vaccine).

Infants and children 6 weeks to less than 15 months of age

Clinical trials were conducted in healthy infants and children 6 weeks to less than 15 months of age using a 3-dose series (Phase 3 trial B7471012 [Study 1012]) or a 4-dose series (Phase 3 trials B7471011 and B7471013 [Studies 1011 and 1013] and the Phase 2 trial B7471003 [Study 1003]). In these 4 infant trials 5156 participants received at least 1 dose of vaccine: 2833 received Prevenar 20 and 2323 received Prevenar 13. Overall, approximately 90% of participants in each group received all doses through the study-specified toddler dose. In all studies, local reactions and systemic events were collected after each dose, and adverse events were collected from the first dose through 1 month after the last infant vaccination and from the toddler dose through 1 month after vaccination

in all studies. Serious adverse events were evaluated through 1 month after the last dose in Study 1012 and 6 months after the last dose in Studies 1011, 1013, and 1003.

The rates of severe local reactions and systemic events were low, and most reactions resolving within 1 to 3 days. The percentages of participants with local reactions and systemic events after Prevenar 20 were generally similar to those after Prevenar 13. Based on the infant data, the most frequently reported local reactions and systemic events after any dose of Prevenar 20 were irritability, drowsiness, and pain at injection site. In these studies, Prevenar 20 was co-administered or permitted to be administered with certain routine pediatric vaccines (see «Interactions»).

Study 1012 was a pivotal, randomized, double-blind, active-controlled Phase 3 trial, in which 601 healthy infants, 2 months (≥42 to ≤112 days) of age and born at >36 weeks of gestation received Prevenar 20 in a 3-dose series. The most frequently reported adverse reactions (>10%) after any dose of Prevenar 20 were irritability (71.0% to 71.9%), drowsiness/increased sleep (50.9% to 61.2%), pain at injection site (22.8% to 42.4%), decreased appetite (24.7% to 39.3%), redness at the injection site (25.3% to 36.9%), swelling at the injection site (21.4% to 29.8%) and fever of ≥38.0°C (8.9% to 24.3%). Most adverse reactions occurred within 1 to 2 days following vaccination and were mild to moderate in severity and of short duration (1 to 2 days).

Studies 1011, 1013 and 1003, were double-blind, randomised, active-controlled trials that included 2232 healthy infants, vaccinated with Prevenar 20 in a 4-dose series. The most frequently reported (>10%) adverse reactions observed after any dose of Prevenar 20 in infants were irritability (58.5% to 70.6%), drowsiness/increased sleep (37.7% to 66.2%), pain at injection site (32.8% to 45.5%), decreased appetite (23.0% to 26.4%), redness at the injection site (22.6% to 24.5%), and swelling at the injection site (15.1% to 17.6%). Most adverse reactions were mild or moderate following vaccination and most reactions resolving within 1 to 3 days. Severe reactions were reported infrequently.

In Study 1013, the local reactions and systemic events in the preterm subgroup (111 infants born at 34 to less than 37 weeks of gestation) were similar to or lower than the term infants in the study. In the preterm subgroup, the frequency of any reported local reaction was 31.7% to 55.3% in the Prevenar 20 group, and any systemic event was 65.0% to 85.5% in the Prevenar 20 group.

Children 15 months to less than 5 years of age

In the Phase 3 trial B7471014 (Study 1014), a total of 831 participants 15 months to less than 18 years of age received a single dose of Prevenar 20 in four age groups (of which 209 participants 15 to less than 24 months of age; 216 participants 2 years to less than 5 years of age). The participants less than 5 years of age had received at least 3 prior doses of Prevenar 13.

The most frequently reported adverse reactions (>10%) observed after any dose of Prevenar 20 in participants less than 2 years of age were irritability (61.8%), pain at the injection site (52.5%), drowsiness/increased sleep (41.7%), redness at the injection site (37.7%), decreased appetite (25.0%), swelling at the injection site (22.1%) and fever ≥38.0°C (11.8%). In participants from 2 years to <5 years of age, the most frequently reported adverse reactions were pain at the injection site (66.0%), redness at the injection site (39.1%), fatigue (37.2%), muscle pain (26.5%) and swelling at the injection site (23.3%).

Individuals 65 years of age and older

The safety of Prevenar 20 was evaluated in 4552 participants 18 years of age and older in six clinical trials (two Phase 1, one Phase 2, and three core Phase 3), and 2496 participants in the control groups. Of these, one Phase 2 included 443 participants 60 to 64 years of age with 221 who received Prevenar 20 and 222 in the control group. Two of the core Phase 3 trials had 4315 participants that were 50 years of age and older with 2465 in Prevenar 20 and 1850 in the control groups.

In the core Phase 3 trials, 2465 participants 50 years of age and older received Prevenar 20. This included 334 participants 50 through 59 years of age, and 2131 participants 60 years of age and older (1138 were 65 years of age and older). Of the participants, 50 years of age and older who received Prevenar 20 in the core Phase 3 trials, 1841 were naïve to pneumococcal vaccines, 253 had previously received PPSV23 (≥1 to ≤5 years prior to enrollment), 246 had previously received Prevenar 13 only (≥6 months prior to enrollment), and 125 had previously received Prevenar 13 followed by PPSV23 (the dose of PPSV23 ≥1-year prior to enrollment).

Participants in the Phase 3 trial B7471007 (Pivotal Study 1007) were evaluated for adverse events for 1 month after vaccination, and serious adverse events through 6 months after vaccination. This study included 445 participants 50 to 59 years of age, 1985 participants 60 to 64 years of age, 624 participants 65 to 69 years of age, 319 participants 70 to 79 years of age, and 69 participants ≥80 years of age.

In participants 50 to 59 years of age in Study 1007, the most frequently reported adverse reactions were pain at injection site (72.5%), muscle pain (49.8%), fatigue (39.3%), headache (32.3%), and joint pain (15.4%). In participants ≥60 years of age in Study 1007, the most frequently reported adverse reactions were pain at injection site (55.4%), muscle pain (39.1%), fatigue (30.2%), headache (21.5%), and joint pain (12.6%). These were usually mild or moderate in intensity and resolved within a few days after vaccination.

Safety data from a pooled analysis of adults ≥65 years of age including both pneumococcal naïve participants (Study 1007) and participants with prior pneumococcal vaccination (Study 1006) included 1885 participants; among these 1138 received Prevenar 20 and 747 received control vaccine. The

safety profile of Prevenar 20 in adults 65 years of age and older with or without prior pneumococcal vaccination was generally similar to control vaccine. MedDRA system organ class (SOC) adverse events for cardiac disorders 1 month after vaccination in participants 65 years of age and older were similar for Prevenar 20 (9 events in 1138 participants (0.8%)) and PPSV23 (1 event in 127 participants (0.8%)), but higher than Prevenar 13 (1 event in 620 participants (0.2%)). At 6 months after vaccination, cardiac events in the SOC were reported for 0.5% of participants (6 events in 1138 participants) who received Prevenar 20.

Phase 3 Study B7471006 (Study 1006) evaluated Prevenar 20 in participants ≥65 years of age with varying prior pneumococcal vaccination status (prior PPSV23, prior Prevenar 13 or prior Prevenar 13 followed by PPSV23). In this study, the most frequently reported adverse reactions for participants were similar in frequency to those described for participants ≥60 years of age in Study 1007, with slightly higher injection site pain (61.2%) in participants with prior Prevenar 13, and joint pain (16.8%) in participants with prior Prevenar 13 followed by PPSV23.

List of adverse reactions

The adverse reactions from the infant Phase 2, Phase 3 clinical trials in pediatric (6 weeks to less than 5 years of age) and adult populations, and post-marketing experience are presented below.

The adverse reactions are listed according to MedDRA system organ classes in decreasing order of frequency and seriousness. The frequency is defined as follows: «very common» (≥1/10), «common» (≥1/100, <1/10), «uncommon» (≥1/1000, <1/100), «rare» (≥1/10’000, <1/1000), «very rare» (<1/10’000) and «not known» (frequency cannot be estimated from the available data).

Adverse reactions from clinical trials

Prevenar 20

As Prevenar 20 contains the same 13 serotype-specific capsular polysaccharide conjugates and the same vaccine excipients as Prevenar 13, the adverse reactions already identified for Prevenar 13 have been adopted for Prevenar 20. Listed below are the adverse reactions reported in the Phase 2 infant trial, and the Phase 3 trials in pediatric (6 weeks to less than 5 years of age) and adult populations, based on the highest frequency among adverse reactions, local reactions, or systemic events after vaccination in a Prevenar 20 group in a study or integrated dataset. The data from clinical trials in infants reflect Prevenar 20 administered simultaneously with other routine childhood vaccines. In the case of adverse reactions reported in clinical trials of Prevenar 13, but not reported in Prevenar 20 trials, the frequency is not known. In clinical trials, the safety profile of Prevenar 20 was similar to that of Prevenar 13.

Pediatric population

Infants and children from 6 weeks to less than 5 years of age

Immune system disorders

Not known: Hypersensitivity reaction including face oedema, dyspnoea, bronchospasm[a].

Metabolism and nutrition disorders

Very common: Decreased appetite (39.3%).

Psychiatric Disorders

Very common: Irritability (71.9%).

Not known: Crying[a].

Nervous system disorders

Very common: Drowsiness/increased sleep (66.2%).

Uncommon: Seizures (including febrile seizures).

Not known: Hypotonic-hyporesponsive episode[a], restless sleep/decreased sleep[a].

Gastrointestinal disorders

Common: Diarrhoea, vomiting.

Skin and subcutaneous tissue disorders

Common: Rash.

Uncommon: Urticaria or urticaria-like rash.

General disorders and administration site conditions

Very common: Fever (pyrexia) (24.3%), vaccination-site pain/tenderness (66.0%), vaccination-site erythema (39.1%), vaccination-site induration/swelling (29.8%), vaccination-site erythema >2.0 cm-

7.0 cm (after toddler dose and in older children [age 2 to 5 years]) (15.3%), vaccination-site induration/swelling >2.0 cm-7.0 cm (after toddler dose and in older children [age 2 to 5 years]) (11.9%).

Common: Fever greater than 38.9°C, vaccination-site induration/swelling >2.0 cm-7.0 cm (after infant series), vaccination-site erythema >2.0 cm-7.0 cm (after infant series), vaccination-site pain/tenderness causing limitation of limb movement.

Uncommon: Vaccination-site erythema (>7.0 cm), vaccination-site induration/swelling (>7.0 cm).

Rare: Vaccination-site hypersensitivity[b].

[a] Adverse reactions reported in Prevenar 13 clinical trials but not reported in Prevenar 20 clinical trials are indicated «not known» for frequency.

[b] Adverse reaction not reported for Prevenar 13, although injection-site urticaria, injection-site pruritus, and injection-site dermatitis were reported in Prevenar 13 postmarketing experience.

Adult population

Immune system disorders

Uncommon: Hypersensitivity reaction, including face oedema, dyspnoea, bronchospasm.

Metabolism and nutrition disorders

Not known: Decreased appetite[c].

Nervous system disorders

Very common: Headache (36.7%).

Gastrointestinal disorders

Uncommon: Diarrhoea[c], nausea, vomiting[c].

Skin and subcutaneous tissue disorders

Uncommon: Rash[c], angioedema.

Musculoskeletal and connective tissue disorders

Very common: Muscle pain (62.9%), joint pain (16.8%).

General disorders and administration site conditions

Very common: Vaccination-site pain/tenderness (79.2%), fatigue (46.7%).

Common: Vaccination-site induration/swelling[c], vaccination-site erythema[c], fever (pyrexia).

Uncommon: Vaccination-site pruritus, lymphadenopathy, vaccination-site urticaria, chills[c].

Not known: Limitation of arm movement[c].

[c] Event reported in clinical trials with Prevenar 13 with very common frequency (≥1/10). Decreased appetite and limitation of arm movement were not reported in the adult Phase 3 trials of Prevenar 20; therefore, the frequency is not known.

Additional information for special populations

No clinical studies with Prevenar 20 have been conducted in premature infants. There are data on the safety of Prevenar 13 in premature infants.

Regarding the risk for apnoea in very premature infants (≤28 weeks of gestation, see «Warnings and precautions»).

In a study comparing approximately 100 prematurely born infants with approximately 100 infants born at term, decreased appetite was significantly more frequent in preterm infants after the 1st and 2nd dose and irritability/decreased sleep was significantly more frequent in preterm infants after the 2nd dose of a three dose primary infant series (see «Properties/Effects»).

Safety with concomitant vaccine administration

Adults

When Prevenar 20 was administered to adults aged ≥65 years together with the third (booster) dose of a COVID-19 mRNA vaccine (nucleoside modified), the tolerability profile generally resembled that of the COVID-19 mRNA vaccine (nucleoside modified) administered alone. There were a few differences in the safety profile when compared to administration of Prevenar 20 alone. In the phase 3 trial B7471026 (Study 1026), pyrexia (13.0%) and chills (26.5%) were reported as «very common» with co-administration. There was also one report of dizziness (0.5%) in the co-administration group.

Prevenar 13

Adults ≥65 years in the clinical efficacy study CAPiTA

The CAPiTA study compared 42’240 individuals ≥65 years vaccinated with Prevenar 13 to 42’256 individuals ≥65 years under placebo.

Among the 84’496 subjects, 58’072 (68.7%) were ≥65 to <75 years of age, 23’481 (27.8%) were ≥75 and <85 years of age, and 2’943 (3.5%) were ≥85 years of age. In the total safety population, more males (55.9%) were enrolled than females. Adults with immunocompromising conditions or receiving immunosuppressive therapy and adults residing in a long-term care facility or requiring semiskilled nursing care were excluded. Adults with pre-existing medical conditions, as well as subjects with a history of smoking were eligible for enrollment. In the safety population, 42.3% of subjects had pre-existing medical conditions including heart disease (25.4%), lung disease or asthma (15.1%) and type 1 and type 2 diabetes mellitus (12.5%). Smoking was reported at baseline by 12.3% of the subjects.

For a subset of 2011 subjects (1006 Prevenar 13 recipients and 1005 placebo recipients), solicited adverse reactions were monitored by recording local and systemic events using electronic diaries for 7 days after vaccination; unsolicited adverse events were collected for 28 days after vaccination, and serious adverse events were collected for 6 months after vaccination. For the remaining 41’231 Prevenar 13 and 41’250 placebo vaccinated subjects, serious adverse events were collected for 28 days after vaccination.

In the CAPiTA study (subjects 65 years and older), serious adverse events within 1 month of vaccination were reported in 327 of 42’237 (0.8%) Prevenar 13 recipients (352 events) and in 314 of 42’225 (0.7%) placebo recipients (337 events). In the subset of subjects where serious adverse events were monitored for 6 months, 70 of 1006 (7%) Prevenar 13 vaccinated subjects (90 events) and 60 of 1005 (6%) placebo vaccinated subjects (69 events) reported serious adverse events.

During the follow-up period (average of 4 years) for case accumulation there were 3006 deaths (7.1%) in the Prevenar 13 group and 3005 deaths (7.1%) in the placebo group. There were 10 deaths (<0.1%) in the Prevenar 13 group and 10 deaths (<0.1%) in the placebo group within 28 days of vaccination. There were 161 deaths (0.4%) in the Prevenar 13 group and 144 deaths (0.3%) in the placebo group within 29 days – 6 months following vaccination.

These data do not provide evidence for a causal relationship between deaths and vaccination with Prevenar 13.

Undesirable effects from the post-marketing phase

Listed below are the adverse experiences that have been spontaneously reported during the post-marketing use of Prevenar 13 in pediatric and adult populations, which may also occur with Prevenar 20. The postmarketing safety experience with Prevenar 13 is relevant to Prevenar 20, as Prevenar 20 contains all components (polysaccharide conjugates and excipients) of Prevenar 13. These events were reported voluntarily from a population of uncertain size. Therefore, it is not possible to reliably estimate their frequency or to establish, for all events, a causal relationship to vaccine exposure.

Blood and lymphatic system disorders

Not known: Lymphadenopathy localized to the region of the vaccination site.

Immune system disorders

Not known: Anaphylactic/anaphylactoid reaction, including shock.

Skin and subcutaneous tissue disorders

Not known: Angioedema, erythema multiforme.

General disorders and administration site conditions

Not known: Vaccination-site dermatitis, vaccination-site urticaria, vaccination-site pruritus.

Reporting suspected adverse reactions after authorisation of the medicinal product is very important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions online via the ElViS portal (Electronic Vigilance System). You can obtain information about this at www.swissmedic.ch.

Overdose

Overdose with Prevenar 20 is unlikely due to its presentation as a pre-filled syringe.

Properties/Effects

ATC code

J07AL02

Mechanism of action

Prevenar 20 contains 20 pneumococcal capsular polysaccharides all conjugated to CRM_{197} carrier protein, which modifies the immune response to the polysaccharide from a T-cell independent response to a T-cell dependent response. The T-cell dependent response leads to a higher antibody response (IgG) and induces functional antibodies (OPA, that are related to opsonization, phagocytosis and killing of pneumococci), to protect against pneumococcal disease. Additionally, the generation of memory B-cells is induced, allowing for an anamnestic (booster) response on re-exposure to the bacterium.

The serotype-specific level of circulating antibodies or OPA titers that correlate with protection against pneumococcal disease have not been clearly defined.

Pharmacodynamics

No information.

Clinical efficacy

No efficacy studies have been performed with Prevenar 20.

For Prevenar (PCV7) there are efficacy data in infants/toddlers in relation to invasive pneumococcal diseases, pneumonia and otitis media from the Northern California Kaiser Permanent (NCKP) and Finnish Otitis Media (FinOM) studies.

Prevenar 13 was approved based on a noninferior immunogenicity compared to PCV7. Approval of Prevenar 20 for the pediatric population is based on comparing the totality of the immune responses in infants after receiving Prevenar 20 to the immune responses after receiving Prevenar 13.

The protective efficacy of Prevenar 20 in adults aged 65 years and older is based on the efficacy demonstrated in the adult immunisation study against community-acquired pneumonia immunisation trial in adults, CAPiTA with 13-valent pneumococcal polysaccharide conjugate vaccine (see «Comparison of immune responses of Prevenar 20 to Prevenar 13»).

For serotypes 8, 10A, 11A, 12F, 15B, 22F and 33F, the indication for adults 65 years and older is approved based on immune responses as measured by opsonophagocytic activity (OPA) assay.

Immunogenicity data

Prevenar 20 clinical trials in the pediatric population

Immunogenicity was assessed by serotype-specific IgG response rates (the proportion of participants meeting the serotype-specific IgG level of ≥0.35 µg/ml or equivalent assay-specific value) and IgG GMCs at 1 month following the primary series and 1 month following the toddler dose. OPA GMTs were also measured 1 month following the primary series and following the toddler dose. The predefined concentration corresponding to 0.35 µg/ml in the WHO ELISA (or equivalent assay-specific threshold value) is only applicable at the population level and cannot be used to predict individual or serotype-specific protection against IPD. No correlate of protection exists for pneumonia and acute otitis media (AOM).

Pneumococcal immune responses after 3 and 4 doses in a 4-dose vaccination series in infants

In Study 1011, conducted in the United States and in Puerto Rico, 1991 healthy infants 2 months (≥42 to ≤98 days) of age at the time of consent and born at >36 weeks of gestation, were enrolled. Participants were randomized (1:1) to receive either Prevenar 20 or Prevenar 13 at approximately 2, 4, 6, and 12 to 15 months of age. Routine pediatric vaccinations were administered concomitantly (see «Interactions»).

Noninferiority of the percentages of participants with predefined serotype-specific IgG concentrations one month after the third infant dose was met for 8 of the 13 serotypes and missed for 5 serotypes (serotypes 1, 3, 4, 9V and 23F) based on a 10% noninferiority criterion. Six of the 7 additional serotypes met the noninferiority criterion; serotype 12F missed the statistical noninferiority criterion (Table 1).

Table 1: Percentage of participants meeting predefined serotype-specific pneumococcal IgG concentrations one month after Dose 3 in participants vaccinated at 2, 4, 6 and 12 through 15 months of age, study 1011[a]

	Prevenar 20 N[b]=831-833	*Prevenar 13 N[b]=801-802*	*Prevenar 20 minus Prevenar 13*
	% (95% CI[c])	*% (95% CI[c])*	*Percentage Difference[d] (95% CI[d,e])*
Serotypes			
1	79.8 (76.9, 82.5)	88.4 (86.0, 90.5)	-8.6 (-12.1, -5.1)
3	52.1 (48.6, 55.5)	67.6 (64.2, 70.8)	-15.5 (-20.1, -10.8)
4	79.7 (76.8, 82.4)	88.2 (85.7, 90.3)	-8.4 (-12.0, -4.9)
5	82.5 (79.7, 85.0)	86.8 (84.2, 89.1)	-4.3 (-7.8, -0.8)
6A	93.5 (91.6, 95.1)	95.9 (94.3, 97.2)	-2.4 (-4.6, -0.2)

	Prevenar 20 N[b]=831-833	*Prevenar 13 N[b]=801-802*	*Prevenar 20 minus Prevenar 13*
	% (95% CI[c])	*% (95% CI[c])*	*Percentage Difference[d] (95% CI[d,e])*
6B	88.3 (85.9, 90.4)	92.4 (90.3, 94.1)	-4.1 (-7.0, -1.2)
7F	96.6 (95.2, 97.8)	97.6 (96.3, 98.6)	-1.0 (-2.7, 0.7)
9V	81.9 (79.1, 84.4)	89.8 (87.5, 91.8)	-7.9 (-11.3, -4.6)
14	93.4 (91.5, 95.0)	94.1 (92.3, 95.7)	-0.8 (-3.1, 1.6)
18C	92.6 (90.6, 94.2)	93.1 (91.2, 94.8)	-0.6 (-3.1, 1.9)
19A	97.1 (95.7, 98.1)	98.1 (96.9, 98.9)	-1.0 (-2.6, 0.5)
19F	96.9 (95.5, 98.0)	96.6 (95.1, 97.8)	0.2 (-1.5, 2.0)
23F	77.9 (74.9, 80.7)	85.5 (82.9, 87.9)	-7.6 (-11.4, -3.9)
Additional Serotypes[f]			
8	96.8 (95.3, 97.9)	[f, g]	11.2 (8.6, 14.0)
10A	82.2 (79.5, 84.8)	[f, g]	-3.3 (-6.9, 0.3)
11A	92.7 (90.7, 94.4)	[f, g]	7.1 (4.2, 10.2)
12F	48.0 (44.6, 51.5)	[f, g]	-37.5 (-41.6, -33.3)
15B	98.2 (97.0, 99.0)	[f, g]	12.7 (10.2, 15.4)
22F	98.3 (97.2, 99.1)	[f, g]	12.8 (10.3, 15.5)
33F	86.7 (84.2, 88.9)	[f, g]	1.1 (-2.2, 4.5)

Abbreviations: CI=confidence interval; IgG = immunoglobulin G.

Note: The predefined IgG concentration was ≥0.35 µg/ml for all serotypes except for serotypes 5, 6B, 12F, and 19A which were ≥0.23 µg/ml, ≥0.10 µg/ml, ≥0.69 µg/ml and ≥0.12 µg/ml respectively.

[a] NCT04382326.

[b] N=number of participants with valid assay results. These values are the denominators for the corresponding percentage calculations.

[c] Exact 2-sided CI, based on the Clopper and Pearson method.

[d] Noninferiority for a serotype was met if the lower bound of the 2-sided CI for the percentage difference (Prevenar 20 minus Prevenar 13)>-10% (10% NI criterion) for that serotype.

[e] 2-Sided CI based on the Miettinen and Nurminen method for the difference in proportions, expressed as a percentage.

[f] For the 7 additional serotypes, the percentage of participants with the predefined IgG concentration to serotype 23F (Prevenar 13 serotype with the lowest percentage, excluding serotype 3) in the Prevenar 13 group was used in the calculation of the percentage difference.

[g] For the 7 additional serotypes, percentages of participants with predefined IgG concentrations to serotypes 8, 10A, 11A, 12F, 15B, 22F and 33F in the Prevenar 13 group were 1.6%, 1.2%, 1.5%, 0.1%, 2.6%, 0.9% and 1.1%, respectively.

One month after the fourth (booster) dose, the IgG GMCs for Prevenar 20 were noninferior for all 13 matched serotypes to Prevenar 13, based on a 2-fold noninferiority criterion (lower bounds of 2-

sided CIs>0.5). The IgG GMCs for all 7 additional serotypes were noninferior to the lowest IgG GMC among Prevenar 13 serotypes (other than serotype 3) based on a 2-fold noninferiority criterion (Table 2). This was also the case for the IgG GMCs for Prevenar 20, one month after the third infant dose (Table 3).

Table 2: Serotype-specific pneumococcal IgG GMCs (µg/ml) and GMC ratios one month after Dose 4 in participants vaccinated at 2, 4, 6 and 12 through 15 months of age, study 1011[a]

	Prevenar 20 N[b]=753-755	*Prevenar 13 N[b]=744-745*	*Prevenar 20/Prevenar 13*
	GMC[c] (95% CI[c])	*GMC[c] (95% CI[c])*	*GMC Ratio[d] (95% CI[d,e])*
Serotypes			
1	1.47 (1.37, 1.57)	2.12 (1.97, 2.27)	0.69 (0.63, 0.76)
3	0.56 (0.53, 0.60)	0.85 (0.80, 0.90)	0.66 (0.61, 0.73)
4	3.77 (3.52, 4.04)	4.84 (4.50, 5.22)	0.78 (0.70, 0.86)
5	1.87 (1.74, 2.00)	2.51 (2.33, 2.70)	0.74 (0.67, 0.82)
6A	9.01 (8.45, 9.61)	11.69 (10.91, 12.53)	0.77 (0.70, 0.85)
6B	4.01 (3.70, 4.35)	5.74 (5.27, 6.24)	0.70 (0.62, 0.79)
7F	3.91 (3.70, 4.14)	5.18 (4.88, 5.49)	0.76 (0.70, 0.82)
9V	3.44 (3.23, 3.67)	4.30 (4.02, 4.59)	0.80 (0.73, 0.88)
14	5.68 (5.27, 6.12)	6.34 (5.88, 6.83)	0.90 (0.81, 1.00)
18C	3.46 (3.24, 3.70)	4.69 (4.34, 5.05)	0.74 (0.67, 0.82)
19A	3.53 (3.30, 3.77)	4.13 (3.84, 4.45)	0.85 (0.77, 0.94)
19F	5.01 (4.68, 5.36)	5.79 (5.36, 6.25)	0.86 (0.78, 0.96)
23F	3.95 (3.63, 4.31)	6.18 (5.66, 6.75)	0.64 (0.57, 0.72)
Additional Serotypes[f]			
8	3.97 (3.73, 4.22)	[f, g]	1.87 (1.71, 2.06)
10A	6.22 (5.75, 6.72)	[f, g]	2.94 (2.64, 3.26)
11A	3.53 (3.31, 3.78)	[f, g]	1.67 (1.51, 1.84)
12F	1.85 (1.73, 1.99)	[f, g]	0.88 (0.79, 0.97)
15B	12.59 (11.78, 13.45)	[f, g]	5.95 (5.39, 6.55)
22F	10.60 (9.92, 11.33)	[f, g]	5.01 (4.54, 5.52)
33F	9.31 (8.71, 9.96)	[f, g]	4.40 (3.99, 4.85)

Abbreviations: CI=confidence interval; GMC=geometric mean concentration; IgG=immunoglobulin G; LLOQ=lower limit of quantitation.

Note: Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.

[a] NCT04382326.

[b] N=Number of participants with valid IgG concentrations.

[c] GMCs and 2-sided CIs were calculated by exponentiating the mean logarithm of the concentrations and the corresponding CIs (based on the Student t distribution).

[d] Noninferiority for a serotype was met if the lower bound of the 2-sided CI of IgG GMC ratio (Prevenar 20/Prevenar 13)>0.5 (2-fold NI criterion) for that serotype.

[e] 2-Sided CIs were calculated by exponentiating the mean differences of the logarithms of the IgG concentrations (Prevenar 20 minus Prevenar 13) and the corresponding CIs (based on the Student t distribution).

[f] For the 7 additional serotypes, the IgG GMC to serotype 1 (Prevenar 13 serotype with the lowest IgG GMC, excluding serotype 3) in the Prevenar 13 group was used in the calculation of the GMC ratio.

[g] For the 7 additional serotypes, the IgG GMCs to serotypes 8, 10A, 11A, 12F, 15B, 22F and 33F in the Prevenar 13 group were 0.03 µg/ml, 0.01 µg/ml, 0.02 µg/ml, 0.01 µg/ml, 0.02 µg/ml, 0.00 µg/ml and 0.01 µg/ml, respectively.

Table 3: Serotype-specific pneumococcal IgG GMCs (µg/ml) and GMC ratios one month after Dose 3 in participants vaccinated at 2, 4, 6 and 12 through 15 months of age, study 1011[a]

Pneumococcal serotype	*Prevenar 20 N[b]=831-833*	*Prevenar 13 N[b]=801-802*	*Prevenar 20/Prevenar 13*
	GMC[c] (95% CI[c])	*GMC[c] (95% CI[c])*	*GMC Ratio[d] (95% CI[d,e])*
Serotype			
1	0.74 (0.70, 0.79)	1.14 (1.06, 1.22)	0.65 (0.59, 0.72)
3	0.36 (0.33, 0.38)	0.51 (0.48, 0.55)	0.70 (0.64, 0.76)
4	0.75 (0.70, 0.81)	1.08 (1.00, 1.17)	0.70 (0.63, 0.78)
5	0.66 (0.61, 0.71)	0.96 (0.88, 1.04)	0.69 (0.61, 0.77)
6A	1.95 (1.81, 2.10)	2.69 (2.48, 2.92)	0.72 (0.65, 0.81)
6B	0.61 (0.55, 0.68)	1.02 (0.91, 1.14)	0.60 (0.51, 0.70)
7F	1.71 (1.62, 1.81)	2.29 (2.16, 2.43)	0.75 (0.69, 0.81)
9V	0.87 (0.81, 0.93)	1.21 (1.12, 1.30)	0.72 (0.65, 0.80)
14	2.16 (2.01, 2.33)	2.72 (2.51, 2.95)	0.79 (0.71, 0.89)
18C	1.31 (1.23, 1.39)	1.71 (1.59, 1.84)	0.77 (0.70, 0.84)
19A	0.72 (0.67, 0.76)	0.91 (0.85, 0.97)	0.79 (0.72, 0.86)
19F	1.59 (1.50, 1.67)	2.00 (1.88, 2.12)	0.79 (0.73, 0.86)
23F	0.82 (0.75, 0.90)	1.25 (1.14, 1.37)	0.66 (0.58, 0.75)
Additional Serotypes[f]			
8	1.80 (1.70, 1.91)	[f, g]	1.98 (1.81, 2.16)
10A	1.21 (1.09, 1.33)	[f, g]	1.32 (1.18, 1.49)
11A	1.39 (1.30, 1.48)	[f, g]	1.52 (1.39, 1.67)
12F	0.55 (0.50, 0.60)	[f, g]	0.60 (0.54, 0.67)
15B	4.40 (4.11, 4.71)	[f, g]	4.82 (4.39, 5.30)
22F	3.71 (3.45, 3.99)	[f, g]	4.06 (3.68, 4.48)
33F	1.49 (1.36, 1.64)	[f, g]	1.64 (1.46, 1.83)

Abbreviations: CI=confidence interval; GMC=geometric mean concentration; IgG=immunoglobulin G; LLOQ=lower limit of quantitation.

Note: Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.

[a] NCT04382326.

[b] N=Number of participants with valid IgG concentrations.

[c] GMCs and 2-sided CIs were calculated by exponentiating the mean logarithm of the concentrations and the corresponding CIs (based on the Student t distribution).

[d] Noninferiority for a serotype was met if the lower bound of the 2-sided CI of IgG GMC ratio (Prevenar 20/Prevenar 13)>0.5 (2-fold NI criterion) for that serotype.

[e] 2-Sided CIs were calculated by exponentiating the mean differences of the logarithms of the IgG concentrations (Prevenar 20 minus Prevenar 13) and the corresponding CIs (based on the Student t distribution).

[f] For the 7 additional serotypes, the IgG GMC to serotype 19A (Prevenar 13 serotype with the lowest IgG GMC, excluding serotype 3) in the Prevenar 13 group was used in the calculation of the GMC ratio.

[g] For the 7 additional serotypes, the IgG GMCs to serotypes 8, 10A, 11A, 12F, 15B, 22F and 33F in the Prevenar 13 group were 0.02 µg/ml, 0.01 µg/ml, 0.02 µg/ml, 0.01 µg/ml, 0.03 µg/ml, 0.01 µg/ml and 0.02 µg/ml, respectively.

The OPA GMTs for the 13 matched serotypes one month after the third infant dose and one month after the booster dose were descriptively evaluated in a subgroup of the participants.

One month after the third infant dose, the OPA GMTs for the 13 matched serotypes in the Prevenar 20 group ranged from 26 (serotype 1) to 1222 (serotype 7F) and the OPA GMTS in the Prevenar 13 group ranged from 34 (serotype 1) to 1149 (serotype 7F). One month after the booster dose, the OPA GMTs for the 13 matched serotypes were slightly lower in the Prevenar 20 group than in the Prevenar 13 group and ranged from 36 (serotype 1) to 2609 (serotype 9V) respectively from 66 (serotype 1) to 3210 (serotype 9V).

The observed OPA GMTs were substantially higher for the 7 additional serotypes at both timepoints in the Prevenar 20 group than in the Prevenar 13 group.

Pneumococcal immune responses after 2 and 3 doses in a 3-dose vaccination series in infants

In Study 1012, the immunogenicity of Prevenar 20 was evaluated in 1204 infants enrolled from Europe and Australia when administered in a series of 2 infant doses and 1 booster dose who were 2 months (≥42 to ≤112 days) of age and born at >36 weeks of gestation. Participants were randomized (1:1) to receive either Prevenar 20 or Prevenar 13 with the first dose given at 42 to 112 days of age, a second dose given approximately 2 months later, and the third (booster) dose given at approximately 11 to 12 months of age. Participants received concomitant vaccines at these visits.

Prevenar 20 elicited immune responses, as assessed by IgG GMCs, percentages of participants with predefined IgG concentrations, and OPA geometric mean titers (GMTs) for all 20 serotypes contained in the vaccine.

One month after the second infant dose of Prevenar 20, the observed IgG GMCs for 9 of the 13 matched serotypes were NI to those in the Prevenar 13 group and 4 of the 13 matched serotypes (6A, 6B, 9V, and 23F) did not meet the 2-fold statistical NI criterion.

The percentages of participants with specified serotype-specific IgG concentrations one month after the second infant dose of Prevenar 20 for 4 of the 13 matched serotypes were noninferior to those of the Prevenar 13 group based on a 10% difference noninferiority criteria; and 9 of the 13 matched serotypes (1, 3, 4, 5, 6A, 6B, 9V, 18C and 23F) did not meet noninferiority.

For the 7 additional serotypes, the percentages of participants with specified serotype-specific IgG concentrations one month after the second infant dose of Prevenar 20 for 5 of the 7 additional serotypes were noninferior to the serotype with the lowest percentage among the 13 serotypes (serotype 6B) in the Prevenar 13 group; serotypes 10A and 12F did not meet the statistical noninferiority criterion. The clinical relevance of these findings is unknown.

Additionally, the IgG GMCs for the 7 additional serotypes were higher compared with the IgG GMCs from the corresponding serotypes in the Prevenar 13 group after two infant doses.

One month after the third (booster) dose, the observed IgG GMCs of Prevenar 20 were noninferior to the Prevenar 13 group for 12 of 13 matched serotypes except for serotype 6B and all 7 additional serotypes were noninferior to the lowest IgG GMC in the Prevenar 13 group. Additionally, the IgG GMCs for the 7 additional serotypes were higher compared with the IgG GMCs from the corresponding serotypes in the Prevenar 13 group after the third (booster) dose.

Functional responses, as measured by OPA GMTs, for the 13 matched serotypes at one month after the second infant dose ranged from 14 (serotype 1) to 858 (serotype 7F) in the Prevenar 20 group and from 23 (serotype 1) to 895 (serotype 7F) in the Prevenar 13 group. Observed OPA GMTs for the 13 matched serotypes at one month after the booster dose ranged from 54 (serotype 1) to 3254 (serotype 9V) in the Prevenar 20 group and from 82 (serotype 5) to 4544 (serotype 9V) in the Prevenar 13 group. The observed OPA GMTs for the 7 additional serotypes both one month after the second infant dose and one month after the booster dose were higher in the Prevenar 20 group than those in the Prevenar 13 group.

Boosting in IgG and OPA antibody responses after Prevenar 20 following Dose 2 to after Dose 3 were observed for all 20 serotypes including those that missed noninferiority, indicative of immunological memory.

Children 12 months to less than 5 years of age previously vaccinated with Prevenar 13

Children 12 months to less than 24 months of age

In a multicenter, randomized, partially double-blinded Phase 3 Study (Study B7471027), the immunogenicity was investigated in 356 toddlers aged 12 months to <24 months of age who received already 2 doses of Prevenar 13 when they were infants. The participants received a single booster dose or 2 booster doses of Prevenar 20 or a booster dose of Prevenar 13. In the group receiving 2 doses of Prevenar 20, the second dose was given approximately 2 months after Dose 1.

After 1 or 2 doses of Prevenar 20 IgG immune responses to all 7 additional serotypes were observed, with the IgG responses to the 7 additional serotypes numerically higher after 2 doses of Prevenar 20 than after a single dose. One month after a single dose of Prevenar 20 the percentage of participants with a predefined serotype-specific IgG concentration (≥0.35 µg/ml) was between 54.6% (serotype 12F) and 98.1% (serotype 8) for the 7 additional serotypes. One month after the second dose of Prevenar 20 the percentage of participants with a predefined serotype-specific IgG concentration was ≥91.2% (serotype12 F).

For Prevenar 20 IgG immune responses to the 13 matched serotypes, the observed IgG GMCs were numerically higher for most of the 13 matched serotypes after 1 dose of Prevenar 20 than after 2 doses of Prevenar 20.

The observed IgG GMC values for the 13 matched serotypes one month after the last vaccination were lower after 1 or 2 doses of Prevenar 20 than after 1 dose of Prevenar 13.

Children 15 months to less than 5 years of age

In a multicenter, single-arm trial (Study 1014), participants were enrolled into the study by age group (approximately 200 participants per group) to receive a single dose Prevenar 20 as described below.

In 15 months to less than 24 months and 2 years to less than 5 years age groups, participants had been previously vaccinated with 3 or 4 doses of Prevenar 13.

Increases in IgG GMCs from before to 1 month after Prevenar 20 were observed for all 20 vaccine serotypes in participants 15 months to less than 24 months of age. The observed IgG GMFRs (geometric mean fold rise) to the 7 additional serotypes ranged from 27.9 to 1847.7. In children 15 months to less than 24 months of age 83.2% to 100.0% had predefined IgG concentrations (≥0.35 µg/ml) to 6 of the 7 additional serotypes, serotype 12F was 40.0%.

Increases in IgG concentrations from before to 1 month after Prevenar 20 were observed for all 20 vaccine serotypes in participants 24 months to less than 5 years of age. The observed IgG GMFRs to the 7 additional serotypes ranged from 36.6 to 796.2.

Preterm infants

The safety and tolerability of Prevenar 20 were evaluated in Study 1013, which included 111 late preterm infants (infants >34 to <37 weeks gestational age) among the total study population. Participants were randomized to receive a 4-dose series of either Prevenar 20 (N=77) or Prevenar 13 (N=34). Studies have not been specifically conducted to describe the immunogenicity of Prevenar 20 in preterm infants. Based on experience with Prevenar and Prevenar 13, immune responses are elicited in preterm infants, although they may be lower than in term infants.

Prevenar 20 clinical trials in the adult population

Three core Phase 3 clinical trials, B7471006, B7471007 and B7471008 (Study 1006, Study 1007, and Study 1008), were conducted in the United States and Sweden evaluating the immunogenicity of Prevenar 20 in different adult age groups, and in participants who were either pneumococcal vaccine-naïve, or previously vaccinated with Prevenar 13, PPSV23 or both.

Each study included participants who were healthy or immunocompetent with stable underlying conditions, including chronic cardiovascular disease, chronic pulmonary disease, renal disorders, diabetes mellitus, chronic liver disease, and medical risk conditions and behaviours (e.g., smoking) that are known to increase the risk of serious pneumococcal pneumonia and IPD. In the pivotal study (Study 1007), these risk factors were identified in 34% of participants 60 years of age and over. A stable medical condition was defined as a medical condition not requiring significant change in therapy in the previous 6 weeks (i.e., change to new therapy category due to worsening disease), or any hospitalization for worsening disease within 12 weeks before receiving the study vaccine.

In each study, immune responses elicited by Prevenar 20 and the control pneumococcal vaccines were measured by an opsonophagocytic activity (OPA) assay. OPA assays measure functional antibodies to *S. pneumoniae*.

Comparison of immune responses of Prevenar 20 to Prevenar 13 and PPSV23

In a randomised, active-controlled, double-blind, noninferiority clinical trial (Pivotal Study 1007) of Prevenar 20, pneumococcal vaccine-naïve participants 18 years of age and older were enrolled into 1 of 3 cohorts based on their age at enrollment (18 to 49, 50 to 59, and ≥60 years of age), and randomised to receive Prevenar 20 or control. Participants 60 years of age and older were randomised in a 1:1 ratio to receive Prevenar 20 (n=1507) followed 1 month later with the administration of saline placebo or Prevenar 13 (n=1490), and with the administration of PPSV23 1 month later.

Serotype-specific OPA GMTs were measured before the first vaccination and 1 month after each vaccination. Noninferiority of immune responses, OPA GMTs 1 month after vaccination, with Prevenar 20 to a control vaccine for a serotype was declared if the lower bound of the 2-sided 95% confidence interval (CI) for the GMT ratio (Prevenar 20/Prevenar 13; Prevenar 20/PPSV23) for that serotype was greater than 0.5.

In participants 60 years of age and older, the immune responses to all 13 matched serotypes elicited by Prevenar 20 were noninferior to those elicited by Prevenar 13 for the same serotypes 1 month after vaccination. In general, numerically lower geometric mean titres were observed with Prevenar 20 in the matched serotypes compared to Prevenar 13 (Table 4), however the clinical relevance of these findings is unknown.

The immune responses induced by Prevenar 20 to 6/7 additional serotypes were noninferior to those induced by PPSV23 to the same serotypes 1 month after vaccination. The response to serotype 8 missed the pre-specified statistical noninferiority criterion (the lower bound of the 2-sided 95% CI for the GMT ratio is 0.49 instead of >0.50) (Table 4). The clinical relevance of this observation is unknown. Supportive analyses for other serotype 8 endpoints in the Prevenar 20 group showed favourable outcomes. These include a GMFR of 22.1 from before vaccination to 1 month post-vaccination, 77.8% of participants achieved a ≥4-fold rise in OPA titres from before vaccination to 1 month after vaccination, and 92.9% of participants achieved OPA titres ≥LLOQ 1 month after vaccination.

Table 4: OPA GMTs 1 month after vaccination in participants 60 years of age and older given Prevenar 20 compared to Prevenar 13 for the 13 matched serotypes and to PPSV23 for the 7 additional serotypes (Study 1007)[a,b,c,d]

	Prevenar 20 (N=1157–1430)	*Prevenar 13 (N=1390–1419)*	*PPSV23 (N=1201–1319)*	*Vaccine Comparison*	
	GMT[e]	*GMT*[e]	*GMT*[e]	*GMT Ratio*[e]	*95% CI*[e]
Serotype					
1	123	154		0.80	0.71, 0.90
3	41	48		0.85	0.78, 0.93
4	509	627		0.81	0.71, 0.93
5	92	110		0.83	0.74, 0.94
6A	889	1165		0.76	0.66, 0.88
6B	1115	1341		0.83	0.73, 0.95
7F	969	1129		0.86	0.77, 0.96
9V	1456	1568		0.93	0.82, 1.05
14	747	747		1.00	0.89, 1.13
18C	1253	1482		0.85	0.74, 0.97
19A	518	645		0.80	0.71, 0.90
19F	266	333		0.80	0.70, 0.91

	Prevenar 20 (N=1157–1430)	*Prevenar 13 (N=1390–1419)*	*PPSV23 (N=1201–1319)*	*Vaccine Comparison*	
	GMT[e]	*GMT*[e]	*GMT*[e]	*GMT Ratio*[e]	*95% CI*[e]
23F	277	335		0.83	0.70, 0.97
Additional Serotypes					
8	466		848	0.55	0.49, 0.62
10A	2008		1080	1.86	1.63, 2.12
11A	4427		2535	1.75	1.52, 2.01
12F	2539		1717	1.48	1.27, 1.72
15B	2398		769	3.12	2.62, 3.71
22F	3666		1846	1.99	1.70, 2.32
33F	5126		3721	1.38	1.21, 1.57

Abbreviations: CI=confidence interval; GMT=geometric mean titre; LLOQ=lower limit of quantitation; N=number of participants; OPA=opsonophagocytic activity; PPSV23=pneumococcal polysaccharide vaccine (23-valent).

[a] Study 1007 was conducted in the United States and in Sweden.

[b] Noninferiority for a serotype was met if the lower bound of the 2-sided 95% CI for the GMT ratio (ratio of Prevenar 20/comparator) was greater than 0.5 (2-fold criterion for noninferiority).

[c] Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.

[d] Evaluable immunogenicity population.

[e] GMTs and GMT ratios as well as the associated 2-sided CIs were based on analysis of log-transformed OPA titres using a regression model with vaccine group, sex, smoking status, age at vaccination in years, and baseline log transformed OPA titres.

A post hoc analysis in Study 1007 participants ≥65 years of age was conducted to evaluate serotype-specific OPA titers 1 month after Prevenar 20 compared to Prevenar 13 for the 13 matched serotypes, and PPSV23 for the 7 additional serotypes in that group. The OPA GMR for each serotype was summarized using the same linear regression model, as in the analysis of the primary immunogenicity objectives in the study population ≥60 years of age. If a 2-fold noninferiority margin (lower bounds of the 2-sided 95% CIs for the model-based OPA GMRs >0.5) as in the primary analysis were applied to the results, all 20 serotypes would have met the statistical noninferiority of Prevenar 20 to Prevenar 13 (or PPSV23) in participants ≥65 years of age.

Immunogenicity of Prevenar 20 in adults previously vaccinated with pneumococcal vaccine

A Phase 3 randomised, open-label clinical trial (Study 1006) described immune responses to Prevenar 20 in participants 65 years of age and older previously vaccinated with PPSV23, with Prevenar 13, or with Prevenar 13 followed by PPSV23. Participants previously vaccinated with

Prevenar 13 (Prevenar 13 only or followed by PPSV23) were enrolled at sites in the United States, whereas participants and previously vaccinated with PPSV23 only were also enrolled from Swedish sites (35.5% in that category).

Prevenar 20 elicited immune responses to all 20 vaccine serotypes in participants 65 years of age and older with prior pneumococcal vaccination (Table 5). Immune responses were lower in participants in both groups who received prior PPSV23 vaccinations.

Table 5: Pneumococcal OPA GMTs before and 1 month after Prevenar 20 in participants 65 years of age and older with prior pneumococcal vaccination (Study 1006)[a,b,c,d]

	Prior PPSV23 only		*Prior Prevenar 13 only*		*Prior Prevenar 13 and PPSV23*	
	Before vaccination (N=208–247)	*After vaccination (N=216–246)*	*Before vaccination (N=210-243)*	*After vaccination (N=201–243)*	*Before vaccination (N=106–121)*	*After vaccination (N=102-121)*
	GMT (95% CI)[e]	*GMT (95% CI)*[e]	*GMT (95% CI)*[e]	*GMT (95% CI)*[e]	*GMT (95% CI)*[e]	*GMT (95% CI)*[e]
Serotype						
1	24 (20, 28)	51 (42, 62)	34 (28, 41)	115 (96, 138)	42 (32, 56)	82 (61, 110)
3	13 (11, 15)	31 (27, 36)	15 (13, 18)	54 (47, 63)	20 (17, 25)	39 (32, 48)
4	29 (23, 35)	150 (118, 190)	67 (53, 84)	335 (274, 410)	73 (53, 101)	194 (143, 262)
5	27 (24, 31)	63 (53, 75)	38 (32, 44)	87 (73, 104)	47 (37, 59)	83 (65, 108)
6A	57 (46, 70)	749 (577, 972)	125 (99, 158)	1081 (880, 1327)	161 (116, 224)	1085 (797, 1478)
6B	107 (86, 133)	727 (574, 922)	174 (138, 219)	1159 (951, 1414)	259 (191, 352)	1033 (755, 1415)
7F	156 (132, 184)	378 (316, 452)	210 (175, 251)	555 (467, 661)	206 (164, 258)	346 (277, 432)
9V	203 (171, 241)	550 (454, 667)	339 (282, 408)	1085 (893, 1318)	352 (270, 459)	723 (558, 938)
14	212 (166, 270)	391 (315, 486)	282 (224, 356)	665 (554, 798)	336 (238, 473)	581 (434, 777)
18C	173 (137, 218)	552 (445, 684)	219 (177, 272)	846 (693, 1033)	278 (209, 369)	621 (470, 821)
19A	82 (66, 100)	239 (197, 288)	124 (100, 153)	365 (303, 440)	182 (141, 235)	341 (264, 439)
19F	61 (52, 71)	159 (131, 192)	89 (74, 107)	242 (199, 294)	120 (94, 154)	218 (168, 282)
23F	23 (18, 28)	152 (115, 199)	48 (37, 62)	450 (358, 566)	66 (46, 94)	293 (204, 420)
Additional Serotypes						
8	55 (45, 67)	212 (172, 261)	28 (24, 33)	603 (483, 753)	139 (99, 195)	294 (220, 392)
10A	212 (166, 269)	1012 (807, 1270)	141 (113, 177)	2005 (1586, 2536)	400 (281, 568)	1580 (1176, 2124)

	Prior PPSV23 only		*Prior Prevenar 13 only*		*Prior Prevenar 13 and PPSV23*	
	Before vaccination (N=208–247)	*After vaccination (N=216–246)*	*Before vaccination (N=210-243)*	*After vaccination (N=201–243)*	*Before vaccination (N=106–121)*	*After vaccination (N=102-121)*
	GMT (95% CI)[e]	*GMT (95% CI)*[e]	*GMT (95% CI)*[e]	*GMT (95% CI)*[e]	*GMT (95% CI)*[e]	*GMT (95% CI)*[e]
11A	510 (396, 656)	1473 (1192, 1820)	269 (211, 343)	1908 (1541, 2362)	550 (386, 785)	1567 (1141, 2151)
12F	147 (112, 193)	1054 (822, 1353)	53 (43, 65)	1763 (1372, 2267)	368 (236, 573)	1401 (1002, 1960)
15B	140 (104, 189)	647 (491, 853)	74 (56, 98)	1480 (1093, 2003)	190 (124, 291)	1067 (721, 1578)
22F	167 (122, 230)	1773 (1355, 2320)	60 (45, 82)	4157 (3244, 5326)	286 (180, 456)	2718 (1978, 3733)
33F	1129 (936, 1362)	2026 (1684, 2437)	606 (507, 723)	3175 (2579, 3908)	1353 (1037, 1765)	2183 (1639, 2908)

Abbreviations: CI=confidence interval; GMT=geometric mean titre; LLOQ=lower limit of quantitation; N=number of participants; OPA=opsonophagocytic activity; PPSV23=pneumococcal polysaccharide vaccine (23-valent).

[a] Study 1006 was conducted in the United States and in Sweden.

[b] Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.

[c] Evaluable immunogenicity population.

[d] Open-label administration of Prevenar 20.

[e] 2-sided CIs based on the Student t distribution.

Pharmacokinetics

Evaluation of pharmacokinetic properties is not required for vaccines.

Absorption

Not applicable

Distribution

Not applicable.

Metabolism

Not applicable.

Elimination

Not applicable.

Preclinical data

Non-clinical data revealed no special hazard for humans based on conventional studies of repeated-dose toxicity and reproduction and developmental toxicity.

Other information

Incompatibilities

In the absence of compatibility studies, this vaccine must not be mixed with other medicinal products.

Shelf life

Do not use this medicine after the expiry date («EXP») stated on the pack.

Special precautions for storage

Store in the refrigerator (2-8 °C). Pre-filled syringes should be stored in the refrigerator horizontally to minimise the resuspension time.

Do not freeze. Discard if the vaccine has been frozen.

From a microbiological point of view, once removed from the refrigerator, the vaccine should be used immediately.

Stability data indicate that the vaccine is stable for 96 h when stored at temperatures from 8 °C to 25 °C, or 72 h when stored at temperatures from 0 °C to 2 °C. At the end of these time periods Prevenar 20 should be used or discarded. These data are intended to guide healthcare professionals in case of temporary temperature excursion only.

Keep out of the reach of children.

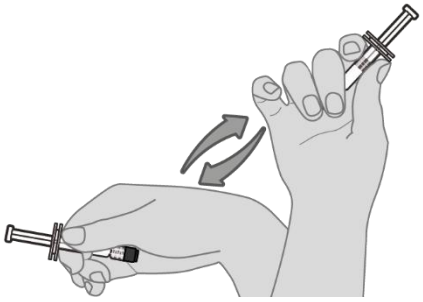
Instructions for handling

During storage, a white deposit and clear supernatant may be observed in the pre-filled syringe containing the suspension. Pre-filled syringes should be stored horizontally to minimise the resuspension time.

Preparation for administration

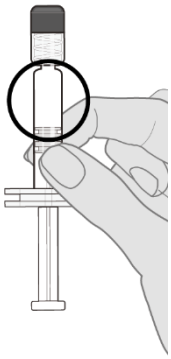
Step 1. Vaccine resuspension

Hold the pre-filled syringe horizontally between the thumb and the forefinger and shake vigorously until the contents of the syringe are a homogeneous white suspension. Do not use the vaccine if it cannot be resuspended.



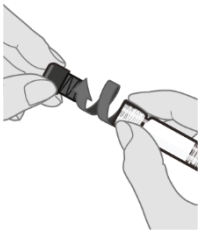
Step 2. Visual inspection

Visually inspect the vaccine for large particulate matter and discolouration prior to administration. Do not use if large particulate matter or discolouration is found. If the vaccine is not a homogenous white suspension, repeat steps 1 and 2.



Step 3. Remove syringe cap

Remove the syringe cap from the Luer lock adapter by slowly turning the cap counter clockwise while holding the Luer lock adapter.



Note: Care should be taken to ensure that the extended plunger rod is not depressed while removing the syringe cap.

Step 4. Attach a sterile needle

Attach a needle appropriate for intramuscular administration to the pre-filled syringe by holding the Luer lock adapter and turning the needle clockwise.

Any unused product or waste material should be disposed of in accordance with local requirements.

Authorisation number

69222 (Swissmedic).

Packs

1 pre-filled syringe of 0.5 ml and 1 needle. [B]

10 pre-filled syringes of 0.5 ml and 10 needles. [B]

Marketing authorisation holder

Pfizer AG, Zürich.

Date of revision of the text

February 2025