PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

PREVNAR 20™

Pneumococcal 20-valent Conjugate Vaccine (Diphtheria CRM_{197} Protein)

Suspension for Intramuscular Injection

One-Dose Syringe (0.5 mL)

Active Immunizing Agent

Pfizer Canada ULC
17,300 Trans-Canada Highway
Kirkland, Quebec H9J 2M5

Date of Initial Authorization:
May 9, 2022

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Sections or subsections that are not applicable at the time of authorization are not listed .

PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

PREVNAR 20 (Pneumococcal 20-valent Conjugate Vaccine [Diphtheria CRM_{197} Protein]) is indicated for active immunization for the prevention of pneumonia and invasive pneumococcal disease (including sepsis, meningitis, bacteremic pneumonia, pleural empyema and bacteremia) caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F in adults 18 years of age and older.

Clinical efficacy for the prevention of pneumonia was studied with PREVNAR 13 for the shared serotypes (see 14 CLINICAL TRIALS), but not for the additional serotypes 8, 10A, 11A, 12F, 15B, 22F, and 33F.

PREVNAR 20 may not prevent disease caused by *S. pneumoniae* serotypes that are not contained in the vaccine.

1.1 Pediatrics

The safety and immunogenicity of PREVNAR 20 in individuals younger than 18 years of age have not been established.

1.2 Geriatrics

PREVNAR 20 has been studied in the geriatric population (see 7.1 Special Populations and 14 CLINICAL TRIALS).

2 CONTRAINDICATIONS

PREVNAR 20 is contraindicated in individuals who are hypersensitive to the active substance or to any component of the vaccine, including diphtheria toxoid. For a complete listing see 6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING.

4 DOSAGE AND ADMINISTRATION

4.1 Dosing Considerations

- Individuals at higher risk of pneumococcal infection, including patients with sickle cell disease or human immunodeficiency virus (HIV) infection, and those previously vaccinated with one or more doses of the 23-valent pneumococcal polysaccharide vaccine (PPSV23), are recommended to receive at least one dose of PREVNAR 20 (see 7 WARNINGS AND PRECAUTIONS, Immune and 14 CLINICAL TRIALS, PREVNAR 13 Immune Responses in Special Populations).

- In individuals with a hematopoietic stem cell transplant (HSCT), the recommended immunization series with PREVNAR 20 consists of four doses of 0.5 mL. The primary series consists of three doses, with the first dose given 3 to 6 months after HSCT and with an interval of at least 1 month between doses. A booster dose is recommended 6 months after the third dose (see 7 WARNINGS AND PRECAUTIONS, Immune and 14 CLINICAL TRIALS, PREVNAR 13 Immune Responses in Special Populations).

- If the sequential use of PPSV23 is considered appropriate, PREVNAR 20 should be given first.

4.2 Recommended Dose and Dosage Adjustment

Adults 18 years of age and older

PREVNAR 20 is administered intramuscularly as a single 0.5 mL dose.

Pediatric population

The safety and immunogenicity of PREVNAR 20 in individuals younger than 18 years of age have not been established.

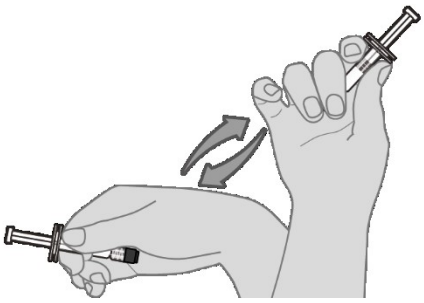
4.4 Administration

Do not mix PREVNAR 20 with any other vaccines or products in the same syringe.

Preparation for administration

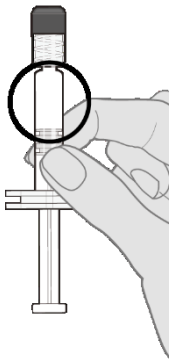
Step 1. Resuspend drug product

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 re-suspended.



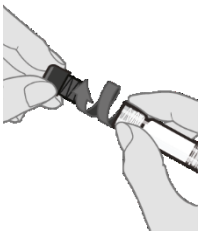
Step 2. Visual inspection

Parenteral drug products should be inspected visually for large particulate matter and discoloration prior to administration. This product should not be used if large particulate matter or discoloration is found. If the suspension does not appear to be a homogeneous 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.

Administration

For intramuscular use only.

Each 0.5 mL dose is to be injected intramuscularly, preferably in the deltoid muscle, with care to avoid injection into or near nerves and blood vessels. The vaccine should not be injected in the gluteal area.

Do not administer PREVNAR 20 intravascularly.

5 OVERDOSAGE

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

For management of a suspected drug overdose, contact your regional poison control centre.

6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

PREVNAR 20 is a homogeneous white suspension for intramuscular injection supplied in a single-dose pre-filled syringe. Each 0.5 mL dose of the vaccine is formulated to contain approximately 2.2 mcg of each of *S. pneumoniae* serotypes 1, 3, 4, 5, 6A, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F and 33F saccharides, 4.4 mcg of 6B saccharide, 51 mcg CRM_{197} carrier protein, 100 mcg polysorbate 80, 295 mcg succinic acid, 4.4 mg sodium chloride, and 125 mcg aluminum as aluminum phosphate adjuvant.

PREVNAR 20 is supplied in cartons of 1 and 10 single-dose pre-filled syringes, without needles.

The tip cap and plunger stopper of the pre-filled syringe are not made with natural rubber latex.

Table 1. Dosage Forms, Strengths, Composition and Packaging

Route of Administration	Dosage Form/ Strength/Composition	Non-medicinal Ingredients
Intramuscular	Suspension for injection 0.5 mL single-dose syringe	Aluminum phosphate Polysorbate 80 Sodium chloride Succinic acid Water for injection

To help ensure the traceability of vaccines for patient immunization record-keeping as well as safety monitoring, health professionals should record the time and date of administration, quantity of administered dose (if applicable), anatomical site and route of administration, brand name and generic name of the vaccine, the product lot number and expiry date.

7 WARNINGS AND PRECAUTIONS

General

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

As with other vaccines, the administration of PREVNAR 20 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.

As with any vaccine, PREVNAR 20 may not protect all individuals receiving the vaccine from pneumococcal disease.

Driving and Operating Machinery

PREVNAR 20 has no or negligible influence on the ability to drive and use machines. However, some of the effects mentioned under **ADVERSE REACTIONS** may temporarily affect the ability to drive or use machines.

Hematologic

As with all injectable vaccines, the vaccine must be administered with caution to individuals with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration.

Immune

Safety and immunogenicity data on PREVNAR 20 are not available for individuals in immunocompromised groups and vaccination should be considered on an individual basis. Studies in individuals with HIV and bone marrow transplant have not been conducted with PREVNAR 20; however, safety and immunogenicity studies with PREVNAR 13 are relevant to PREVNAR 20, since the vaccines are manufactured similarly and contain 13 of the same polysaccharide conjugates (see 14 CLINICAL TRIALS).

Based on experience with pneumococcal vaccines, some individuals with altered immunocompetence may have reduced immune responses to PREVNAR 20. Individuals with impaired immune responsiveness, 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.

Reproductive Health: Female and Male Potential

No human data on the effect of PREVNAR 20 on fertility are available.

Animal studies do not indicate direct or indirect harmful effects with respect to female fertility or reproductive toxicity (see 16 NON-CLINICAL TOXICOLOGY).

7.1 Special Populations

7.1.1 Pregnant Women

Safety during pregnancy has not been established in humans.

7.1.2 Breast-feeding

Safety during lactation has not been established in humans.

It is not known whether vaccine antigens or antibodies are excreted in human milk.

7.1.3 Pediatrics

The safety and immunogenicity of PREVNAR 20 in individuals younger than 18 years of age have not been established.

7.1.4 Geriatrics

Of the 4,263 adults in the three Phase 3 studies of the clinical development program who received PREVNAR 20, 668 (15.7%) were 65 through 69 years of age, 398 (9.3%) were 70 through 79 years of age, and 72 (1.7%) were 80 years of age and older. PREVNAR 20 has been shown to be safe and immunogenic in the geriatric population regardless of prior pneumococcal vaccination (see 14 CLINICAL TRIALS).

8 ADVERSE REACTIONS

8.1 Adverse Reaction Overview

The safety profile is based on the analysis of three Phase 3 clinical trials (see 14 CLINICAL TRIALS). There were 4,263 adult participants who received PREVNAR 20, which included 3,639 adults that were naïve to pneumococcal vaccines, 253 that had previously received the 23-valent pneumococcal polysaccharide vaccine, (Pneumovax® 23 [PPSV23]) only, 246 that had previously received PREVNAR 13 only, and 125 that had previously received both PPSV23 and PREVNAR 13. The most commonly reported solicited adverse reactions (>10%) were vaccination-site pain/tenderness, muscle pain, fatigue, headache and joint pain. Overall, the serious adverse events (SAEs) reported were consistent with diseases and conditions observed in adults of different age groups, and none were considered to be related to the study vaccine. In all three Phase 3 trials, PREVNAR 20 demonstrated a tolerability and safety profile similar to that of PREVNAR 13.

8.2 Clinical Trial Adverse Reactions

Clinical trials are conducted under very specific conditions. The adverse reaction rates observed in the clinical trials, therefore, may not reflect the rates observed in practice and should not be compared to the rates in the clinical trials of another drug. Adverse reaction information from clinical trials may be useful in identifying and approximating rates of adverse drug reactions in real-world use.

Solicited Adverse Reactions

The frequency of solicited adverse reactions in adults <65 years of age naïve to pneumococcal vaccination and in adults ≥65 years of age by prior pneumococcal vaccination status are shown in Table 2 and Table 3, respectively. Local adverse reactions (redness, swelling, and pain at the injection site) were prompted daily for 10 consecutive days after vaccination. Systemic adverse events (fever, fatigue, headache, muscle pain, and joint pain) were prompted daily for 7 days after vaccination.

In general, the median onset day for local reactions was between Day 1 (day of vaccination) to Day 2.5, and they resolved with a median duration of 1 to 2 days. The median onset day for most systemic events was generally between Day 1 to Day 3.5, and they resolved with a median duration of 1 to 2 days.

Table 2. Solicited Local Adverse Reactions and Systemic Events After Vaccination in Pneumococcal Vaccine Naïve Adults <65 Years of Age from Studies 1007 and 1008

Adverse Reaction[b]	Study 1007 60-64 Years of Age		Study 1007 50-59 Years of Age		Study 1007 and Study 1008 18-49 Years of Age	
	PREVNAR 20 (N[a]=991) %	PREVNAR 13 (N[a]=990) %	PREVNAR 20 (N[a]=331) %	PREVNAR 13 (N[a]=111) %	PREVNAR 20 (N[a]=1791) %	PREVNAR 13 (N[a]=355) %
Local Reaction						
Redness	7.1	6.3	8.2	5.4	7.4	7.3
Swelling	8.0	8.3	8.8	10.8	9.1	9.9
Pain at injection site	61.6	59.2	72.5	69.4	79.2	77.7
Systemic Event						
Fever ≥38.0°C	0.8	0.4	1.5	0.9	1.2	1.1
Fever >40.0°C	0.2	0	0.3	0	0	0
Fatigue	32.7	32.4	39.3	36.0	46.7	43.7
Headache	24.5	25.3	32.3	36.0	36.7	36.6
Muscle pain	42.8	39.8	49.8	49.5	62.9	64.8
Joint pain	12.2	14.5	15.4	20.7	16.2	15.2

a. N = number of participants with any e-diary data reported after vaccination.
b. Local reactions solicited within 10 days after vaccination; systemic events solicited within 7 days after vaccination.

Table 3. Solicited Local Adverse Reactions and Systemic Events After Vaccination in Adults ≥65 Years of Age by Prior Pneumococcal Vaccination Status from Studies 1006 and 1007

Adverse Reaction[b.]	Study 1007		Study 1006				
	Prior Pneumococcal Vaccination Status[c]						
	Naïve		PPSV23		PREVNAR 13		PREVNAR 13 & PPSV23
	PREVNAR 20 (N[a]=514) %	PREVNAR 13 (N[a]=493) %	PREVNAR 20 (N[a]=253) %	PREVNAR 13 (N[a]=121) %	PREVNAR 20 (N[a]=245) %	PPSV23 (N[a]=126) %	PREVNAR 20 (N[a]=125) %
Local Reaction							
Redness	7.8	6.1	7.9	2.5	8.6	12.7	4.8
Swelling	6.6	7.3	9.9	6.6	9.4	14.3	4.0
Pain at injection site	43.6	44.0	50.2	43.0	61.2	56.3	52.8
Systemic Event							
Fever ≥38.0°C	1.2	1.6	0.8	0	0	1.6	0
Fever >40.0°C	0.6	0.6	0	0	0	0	0
Fatigue	25.3	27.2	28.9	22.3	31.0	33.3	32.8
Headache	15.8	19.3	17.8	18.2	13.5	21.4	19.2
Muscle pain	31.9	32.3	32.0	31.4	33.9	46.0	37.6
Joint pain	13.4	12.0	6.7	10.7	11.8	15.9	16.8

a. N = number of participants with any e-diary data reported after vaccination.
b. Local reactions solicited within 10 days after vaccination; systemic events solicited within 7 days after vaccination.
c. Includes participants who previously received either PPSV23 ≥1 to ≤5 years before enrollment (PPSV23), PREVNAR 13 ≥6 months before enrollment (PREVNAR 13), or PREVNAR 13 followed by PPSV23 ≥1 year before enrollment (PREVNAR 13 and PPSV23) in the study.

Additional Information in Immunocompromised Patients in Studies with PREVNAR 13

Adults 18 years and older with HIV infection who received PREVNAR 13 had similar frequencies of adverse reactions as adults 50 years of age and older who received PREVNAR 13, except that fever and vomiting had a frequency category of Very Common (≥1/10) and nausea had a frequency category of Common (≥1/100 to <1/10).

Adults 18 years and older with a hematopoietic stem cell transplant who received PREVNAR 13 had similar frequencies of adverse reactions as adults 18 years and older who received PREVNAR 13, except that fever and vomiting had a frequency category of Very Common (≥1/10).

8.3 Less Common Clinical Trial Adverse Reactions

Listed below are the less common adverse reactions reported in clinical trials with PREVNAR 20 (Uncommon frequency ≥1/1,000 to < 1/100).

Immune system disorders: Hypersensitivity reaction, including face edema, dyspnea, bronchospasm

Gastrointestinal disorders: Diarrhea, nausea, vomiting

Skin and subcutaneous tissue disorders: Rash, angioedema

General disorders and administration site conditions: Vaccination-site pruritus, lymphadenopathy, vaccination-site urticaria, chills

8.5 Post-Market Adverse Reactions

Post-marketing Experience with PREVNAR 13

The following adverse reactions have been reported since market introduction of PREVNAR 13, and are included based on one or more of the following factors: severity, frequency of reporting, or strength of evidence for a causal relationship to PREVNAR 13. Although these adverse reactions reported in the post-marketing experience of PREVNAR 13 were not observed in the PREVNAR 20 clinical trials, they are considered possible adverse reactions for PREVNAR 20 as the components of PREVNAR 13 are also contained in PREVNAR 20.

Table 4. Adverse Reactions From PREVNAR 13 Post-marketing Experience

System Organ Class	Frequency Not Known
Immune system disorders	Anaphylactic/anaphylactoid reaction including shock
Skin and subcutaneous tissue disorders	Erythema multiforme
General disorders and administration site conditions	Vaccination-site dermatitis

9 DRUG INTERACTIONS

No data are currently available regarding concomitant use of PREVNAR 20 with other vaccines.

If PREVNAR 20 is administered at the same time as another injectable vaccine, the vaccines should always be administered with different syringes and given at different injection sites.

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

10 CLINICAL PHARMACOLOGY

10.1 Mechanism of Action

S. pneumoniae (pneumococcus) is a gram-positive diplococcus that can cause invasive disease including meningitis, sepsis, and pneumonia with bacteremia and non-invasive disease such as pneumonia without bacteremia. Non-bacteremic pneumococcal pneumonia accounts for the majority of pneumococcal disease cases among the adult population. Over 90 different serotypes of pneumococcus have been identified. The serotypes included in PREVNAR 20 were selected based on their relevance in causing global disease and have been associated with higher case fatality rates and mortality, antibiotic resistance, meningitis and outbreaks.

PREVNAR 20 contains 20 pneumococcal capsular polysaccharides all conjugated to a 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 both an enhanced antibody response and generation of memory B cells, allowing for an anamnestic (booster) response on re-exposure to bacterial polysaccharide. In the absence of T-cell help, plain polysaccharide (PS) stimulated B-cells predominantly produce IgM antibodies; there is generally no affinity maturation of the antibodies, and no memory B-cells are generated. As vaccines, PSs are associated with poor or absent immunogenicity in infants less than 24 months of age and failure to induce immunological memory at any age.

Vaccination with PREVNAR 20 induces serum antibody production and immunologic memory against the serotypes contained within the vaccine. In adults, the levels of circulating antibodies that correlate with protection against pneumococcal disease have not been clearly defined.

11 STORAGE, STABILITY AND DISPOSAL

Store in a refrigerator between 2°C and 8°C (36°F to 46°F).

Syringes should be stored in the refrigerator horizontally to minimize the re-dispersion time.

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

PREVNAR 20 should be administered as soon as possible after being removed from refrigeration.

PREVNAR 20 can be administered provided total (cumulative multiple excursions) time out of refrigeration (at temperatures between 8°C and 25°C) does not exceed 96 hours.

Cumulative multiple excursions between 0°C and 2°C are also permitted as long as the total time between 0°C and 2°C does not exceed 72 hours. These are not, however, recommendations for storage.

12 SPECIAL HANDLING INSTRUCTIONS

During storage, a white deposit and clear supernatant may be observed in the pre-filled syringe containing the suspension. Syringes should be stored horizontally to minimize the re-dispersion time.

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

PART II: SCIENTIFIC INFORMATION

13 PHARMACEUTICAL INFORMATION

Drug Substance

PREVNAR 20 (Pneumococcal 20-valent Conjugate Vaccine [Diphtheria CRM_{197} Protein]) is a sterile suspension of saccharides of the capsular antigens of *S. pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F, each individually linked to non-toxic diphtheria CRM_{197} protein.

Product Characteristics

Each serotype is grown in soy peptone broth, and the individual polysaccharides are purified by a series of chemical and physical methods. The polysaccharides are chemically activated and then directly conjugated to the carrier protein CRM_{197}, to form the glycoconjugate. CRM_{197} is a non-toxic variant of diphtheria toxin isolated from cultures of *Corynebacterium diphtheriae* strain C7 (β_{197}). The individual glycoconjugates are purified by a series of chemical and physical methods and compounded to formulate PREVNAR 20.

Each 0.5 mL dose of the vaccine is formulated to contain approximately 2.2 mcg of each of *S. pneumoniae* serotypes 1, 3, 4, 5, 6A, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, 33F saccharides, and 4.4 mcg of 6B saccharide, individually conjugated to CRM_{197} carrier protein (approximately 51 mcg/dose) and adsorbed on aluminum phosphate (0.125 mg aluminum/dose).

14 CLINICAL TRIALS

14.1 Trial Design and Study Demographics

PREVNAR 20 Clinical Trials in Adults

Three Phase 3 clinical trials (Study 1006, Study 1007, and Study 1008) were conducted in the United States and Sweden evaluating the safety and immunogenicity of PREVNAR 20 in adults of different age groups, including individuals who were either pneumococcal vaccine naïve (Studies 1007 and 1008) or who were previously vaccinated with PREVNAR 13, PPSV23, or both (Study 1006).

Each study included healthy adults and immunocompetent adults with stable underlying conditions including chronic cardiovascular disease, chronic pulmonary disease, renal disorders, diabetes mellitus, chronic liver disease, and medical risk conditions and behaviors (e.g., smoking) that are known to increase the risk of serious pneumococcal pneumonia and invasive pneumococcal disease (IPD).

In each study, immune responses elicited by PREVNAR 20 and the control pneumococcal vaccines were measured before and one month after vaccination by an opsonophagocytic activity (OPA) assay. Serotype-specific OPA assays measure functional antibodies to *S pneumoniae,* and OPA titer is the reciprocal of the highest serum dilution resulting in 50% reduction in the number of bacterial colony forming units compared to control without serum.

Table 5. Summary of Patient Demographics for Clinical Trials in Adults

Study #	Study design	Dosage, route of administration	Study subjects (n)[a]	Demographics
B7471007	Phase 3, multicenter, randomized, double-blind study with an age-based 3-cohort design	Cohort 1: One IM dose of 20vPnC/Saline or 13vPnC/PPSV23 (Vaccination 1/ Vaccination 2) Cohorts 2 and 3: One IM dose of 20vPnC or 13vPnC	Cohort 1 (≥60 years) 20vPnC/saline: 1507 13vPnC/PPSV23: 1490 Cohort 2 (50-59 years) 20vPnC: 334 13vPnC: 111 Cohort 3 (18-49 years) 20vPnC: 335 13vPnC: 112	Cohort 1: Sex: 1221 M/1776 F Age: mean (min/max): 64.6 (60/91) years Cohort 2: Sex: 181 M/264 F Age: mean (min/max): 54.9 (48[b]/59) years Cohort 3: Sex: 156 M/291 F Age: mean (min/max): 34.0 (18/60[b]) years
B7471006	Phase 3, multicenter, randomized, open-label study with a 3-cohort design based on prior pneumococcal vaccination status	Cohort A: One IM dose of 20vPnC or 13vPnC Cohort B: One IM dose of 20vPnC or PPSV23 Cohort C: One IM dose of 20vPnC	Cohort A: (prior vaccination with PPSV23 ≥1 year and ≤5 years) 20vPnC: 253 13vPnC: 122 Cohort B: (prior vaccination with 13vPnC ≥6 months) 20vPnC: 246 13vPnC: 127 Cohort C: (prior vaccination with 13vPnC followed by PPSV23) 20vPnC: 125	Cohort A: Sex: 171 M/204 F Age: mean (min/max): 69.8 (65/84) years Cohort B: Sex: 167 M/206 F Age: mean (min/max): 70.7 (65/92) years Cohort C: Sex: 60 M/65 F Age: mean (min/max): 70.8 (65/81) years
B7471008	Phase 3, multicenter, randomized, double-blind, lot consistency study with a 4-arm parallel design	One IM dose of 20vPnC (Lot 1, 2 or 3) or 13vPnC	18-49 years, pneumococcal vaccine naïve Pooled 20vPnC: 1463 13vPnC: 245	Pooled 20vPnC: Sex: 492 M/971 F Age: mean (min/max): 35.4 (18/49) years 13vPnC: Sex: 101 M/144 F Age: mean (min/max): 35.0 (18/49) years

Abbreviations: 20vPnC: PREVNAR 20; 13vPnC: PREVNAR 13; PPSV23: 23-valent pneumococcal polysaccharide vaccine; M: male; F: female

a. Number of subjects vaccinated.

b. One subject was incorrectly enrolled in Cohort 3 (18-49 years of age) rather than Cohort 1 (≥60 years of age), and one subject was incorrectly enrolled in Cohort 2 (50-59 years of age) rather than Cohort 3 (18-49 years of age).

Study 1007

The pivotal Study 1007 was a non-inferiority study consisting of a main Cohort 1 of participants 60 years of age and older, randomized (1:1) to receive a single dose of either PREVNAR 20 (Vaccination 1) followed 1 month later with administration of saline placebo (Vaccination 2), or PREVNAR 13 (Vaccination 1) followed 1 month later with a dose of PPSV23 (Vaccination 2). The other two younger cohorts, participants 50 through 59 years of age (Cohort 2) and participants 18 through 49 years of age (Cohort 3), were randomized (3:1) either to receive a single dose of PREVNAR 20 or PREVNAR 13.

Serotype-specific OPA geometric mean titers (GMTs) were measured before the first vaccination and one month after each Vaccination 1 or 2. In Cohort 1, non-inferiority of immune responses with PREVNAR 20 to a control vaccine (PREVNAR 13 or PPSV23) for each serotype OPA GMT on the natural log scale was declared if the lower bound of the 2 sided 95% confidence interval (CI) for the GMT ratio (geometric mean ratio; GMR) was greater than 0.5. A linear regression model that included terms for age, baseline OPA titer, sex, smoking status and vaccine group was used to calculate the GMRs. Similarly, the OPA titers from the younger Cohorts 2 and 3 were declared non-inferior to those from subjects aged 60 to 64 years from Cohort 1 for each PREVNAR 20 serotype, if the lower 2-sided 95% confidence limit for the serotype-specific OPA GMR exceeded 0.5.

Study 1006

Study 1006 described immune responses to PREVNAR 20 in adults 65 years of age and older previously vaccinated with PPSV23 between ≥1 to ≤5 years prior to enrollment (Cohort A), previously vaccinated with PREVNAR 13 ≥6 months prior to enrollment (Cohort B), and previously vaccinated with PREVNAR 13 followed by PPSV23 ≥1 year prior to enrollment (Cohort C). Participants in Cohorts A and B were randomized (2:1) to receive either a single dose of PREVNAR 20 or control pneumococcal vaccine (PREVNAR 13 or PPSV23, respectively). In Cohort C, participants only received a single dose of PREVNAR 20. There was no formal hypothesis testing for any safety or immunogenicity endpoint.

Study 1008

The safety and immunogenicity of three different lots of PREVNAR 20 were compared in pneumococcal vaccine naïve adults 18 through 49 years of age. Participants received a single dose of PREVNAR 20. The 3 different lots of PREVNAR 20 elicited equivalent immune responses for the 20 vaccine serotypes (data not shown).

14.2 Study Results

Study 1007

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

In adults 60 years of age and older, immune responses to all 13 matched serotypes elicited by PREVNAR 20 were non-inferior to the immune responses to the same serotypes elicited by PREVNAR 13 in the evaluable immunogenicity population 1 month after vaccination (Table 6). Immune responses to 6 out of the 7 additional serotypes induced by PREVNAR 20 were non-inferior to the immune responses to these same serotypes induced by PPSV23 one month after vaccination. The response to serotype 8 missed the pre-specified statistical non-inferiority criterion of >0.5 GMR for the lower bound of the 95% CI with a GMR of 0.49.

It is however noted that the immune response to serotype 8 was within the range observed for the 13 serotypes in the PREVNAR 13 group. The geometric mean fold rise (GMFR) in OPA titers for serotype 8

(GMFR of 22.1) was within the range observed for the 13 serotypes in the PREVNAR 13 group (GMFRs of 5.8 to 42.6). The same trend was also observed both in the percentage of participants with a ≥4-fold rise in OPA titers: 77.8% for serotype 8 in the PREVNAR 20 group, within the range of 54.0% to 84.0% across the 13 serotypes in the PREVNAR 13 group, and the percentage of participants with OPA titers ≥ lower limit of quantitation (LLOQ) at 1 month after vaccination: 92.9% for serotype 8 in the PREVNAR 20 group, within the range of 76.0% to 96.6% across the 13 serotypes in the PREVNAR 13 group.

Table 6. OPA GMTs and GMRs 1 Month After Vaccination in Adults 60 Years of Age and Older Given PREVNAR 20 Compared to PREVNAR 13 for the 13 Matched Serotypes and PPSV23 for the 7 Additional Serotypes (Study 1007)[a]

	PREVNAR 20	PREVNAR 13	PPSV23	Vaccine Comparison
	GMT[b]	GMT[b]	GMT[b]	GMR (95% CI)[b]
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)
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; GMR = geometric mean ratio; GMT = geometric mean OPA titer; OPA = opsonophagocytic activity; PPSV23 = 23-valent pneumococcal polysaccharide vaccine.

a. Non-inferiority for a serotype was met if the lower bound of the 2-sided 95% CI for the GMT ratio (ratio of PREVNAR 20/comparator) was greater than 0.5 (2-fold criterion for non-inferiority).

b. GMTs and GMRs as well as the associated 2-sided CIs were based on the analysis of log-transformed OPA titers using a regression model with vaccine group, sex, smoking status, age at vaccination, and baseline OPA titers.

Immunogenicity in adults 18 through 59 years of age

PREVNAR 20 elicited immune responses to all 20 vaccine serotypes 1 month after vaccination in both of the younger age groups (Cohorts 2 and 3), and all were non-inferior to responses in adults 60 through 64 years of age (Table 7).

Table 7. Comparisons of OPA GMTs 1 Month After PREVNAR 20 in Adults 18 Through 49 or 50 Through 59 Years of Age to Adults 60 Through 64 Years of Age (Study 1007)[a]

	18–49 Years	60–64 Years	18–49 Years / 60–64 Years	50–59 Years	60–64 Years	50–59 Years / 60–64 Years
	GMT[b]	GMT[b]	GMR (95% CI)[b]	GMT[b]	GMT[b]	GMR (95% CI)[b]
Serotype						
1	163	132	1.23 (1.01, 1.50)	136	132	1.03 (0.84, 1.26)
3	42	42	1.00 (0.87, 1.16)	43	41	1.06 (0.92, 1.22)
4	1967	594	3.31 (2.65, 4.13)	633	578	1.10 (0.87, 1.38)
5	108	97	1.11 (0.91, 1.36)	85	97	0.88 (0.72, 1.07)
6A	3931	1023	3.84 (3.06, 4.83)	1204	997	1.21 (0.95, 1.53)
6B	4260	1250	3.41 (2.73, 4.26)	1503	1199	1.25 (1.00, 1.56)
7F	1873	1187	1.58 (1.30, 1.91)	1047	1173	0.89 (0.74, 1.07)
9V	6041	1727	3.50 (2.83, 4.33)	1726	1688	1.02 (0.83, 1.26)
14	1848	773	2.39 (1.93, 2.96)	926	742	1.25 (1.01, 1.54)
18C	4460	1395	3.20 (2.53, 4.04)	1805	1355	1.33 (1.06, 1.68)
19A	1415	611	2.31 (1.91, 2.81)	618	600	1.03 (0.85, 1.25)
19F	655	301	2.17 (1.76, 2.68)	287	290	0.99 (0.80, 1.22)
23F	1559	325	4.80 (3.65, 6.32)	549	328	1.68 (1.27, 2.22)
Additional Serotypes						
8	867	508	1.71 (1.38, 2.12)	487	502	0.97 (0.78, 1.20)
10A	4157	2570	1.62 (1.31, 2.00)	2520	2437	1.03 (0.84, 1.28)
11A	7169	5420	1.32 (1.04, 1.68)	6417	5249	1.22 (0.96, 1.56)
12F	5875	3075	1.91 (1.51, 2.41)	3445	3105	1.11 (0.88, 1.39)
15B	4601	3019	1.52 (1.13, 2.05)	3356	2874	1.17 (0.88, 1.56)
22F	7568	4482	1.69 (1.30, 2.20)	3808	4228	0.90 (0.69, 1.17)
33F	7977	5693	1.40 (1.10, 1.79)	5571	5445	1.02 (0.81, 1.30)

a. Non-inferiority for a serotype was met if the lower bound of the 2-sided 95% CI for the GMR (ratio of younger age group/60 through 64 years of age group) was greater than 0.5 (2-fold criterion for non-inferiority).

b. GMTs, GMRs, and the associated 2-sided CIs were based on the analysis of log-transformed OPA titers using regression models with age group, sex, smoking status, and baseline OPA titers.

Study 1006

Immunogenicity of PREVNAR 20 in adults previously vaccinated with pneumococcal vaccine

PREVNAR 20 elicited immune responses to all 20 vaccine serotypes in adults 65 years of age and older with prior pneumococcal vaccination (Table 8).

Table 8. Pneumococcal OPA GMTs and GMFRs from Before to 1 Month After PREVNAR 20 in Adults 65 Years of Age and Older With Prior Pneumococcal Vaccination (Study 1006)

	Prior PPSV23			Prior PREVNAR 13			Prior PREVNAR 13 & PPSV23		
	GMT[a]		GMFR[a] (95% CI)	GMT[a]		GMFR[a] (95% CI)	GMT[a]		GMFR[a] (95% CI)
	Before	After		Before	After		Before	After	
Serotype									
1	24	51	2.2 (1.9, 2.5)	34	115	3.4 (2.9, 4.1)	41	82	2.0 (1.7, 2.4)
3	13	31	2.4 (2.1, 2.8)	15	54	3.5 (3.1, 4.1)	20	39	1.9 (1.6, 2.3)
4	30	146	4.9 (3.9, 6.1)	67	334	5.0 (4.1, 6.2)	78	191	2.4 (1.9, 3.1)
5	27	62	2.3 (2.0, 2.6)	38	87	2.3 (2.0, 2.6)	47	84	1.8 (1.5, 2.0)
6A	58	731	12.6 (9.5, 16.7)	127	1051	8.3 (6.6, 10.4)	161	1048	6.5 (4.7, 9.1)
6B	109	720	6.6 (5.2, 8.4)	176	1179	6.7 (5.4, 8.3)	259	1030	4.0 (3.0, 5.2)
7F	161	367	2.3 (1.9, 2.7)	210	545	2.6 (2.2, 3.0)	205	337	1.6 (1.4, 2.0)
9V	206	503	2.4 (2.1, 2.9)	347	1058	3.1 (2.6, 3.6)	345	721	2.1 (1.7, 2.6)
14	213	386	1.8 (1.5, 2.1)	286	660	2.3 (1.9, 2.8)	342	581	1.7 (1.4, 2.1)
18C	175	552	3.2 (2.5, 3.9)	217	846	3.9 (3.2, 4.8)	273	611	2.2 (1.8, 2.7)
19A	84	241	2.9 (2.4, 3.4)	124	356	2.9 (2.4, 3.4)	184	345	1.9 (1.6, 2.2)
19F	61	160	2.6 (2.2, 3.1)	89	242	2.7 (2.3, 3.2)	118	218	1.9 (1.5, 2.3)
23F	23	151	6.6 (5.1, 8.5)	48	447	9.3 (7.4, 11.8)	64	288	4.5 (3.4, 6.0)
Additional Serotypes									
8	58	207	3.6 (2.9, 4.4)	27	609	22.5 (17.2, 29.4)	137	292	2.1 (1.6, 2.8)
10A	212	956	4.5 (3.5, 5.7)	134	1923	14.4 (10.9, 19.0)	360	1595	4.4 (3.3, 6.0)
11A	532	1348	2.5 (2.0, 3.2)	270	1807	6.7 (5.0, 9.0)	491	1514	3.1 (2.2, 4.4)
12F	139	1000	7.2 (5.5, 9.5)	53	1684	31.7 (23.1, 43.4)	358	1367	3.8 (2.7, 5.5)
15B	145	625	4.3 (3.3, 5.7)	74	1402	18.9 (13.0, 27.4)	199	956	4.8 (3.1, 7.5)
22F	161	1779	11.1 (8.0, 15.3)	61	4099	66.9 (46.5, 96.4)	266	2616	9.8 (6.2, 15.6)
33F	1137	2059	1.8 (1.5, 2.2)	564	3041	5.4 (4.2, 6.8)	1269	2234	1.8 (1.4, 2.2)

Abbreviations: GMT = geometric mean OPA titer; GMFR = geometric mean fold rise

a. GMTs, GMFRs and the corresponding 2-sided CIs were calculated by exponentiating the mean logarithm of the titers or fold rises and the corresponding CIs based on the Student t distribution. GMTs and GMFRs were calculated from those with valid OPA titers at both before and 1 month after vaccination timepoints.

14.4 Immunogenicity

The efficacy of PREVNAR 13 against serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F is relevant to PREVNAR 20, since the vaccines are manufactured similarly and contain 13 of the same polysaccharide conjugates.

PREVNAR 13 CAPiTA Efficacy Study

The efficacy of PREVNAR 13 against vaccine-type (VT) pneumococcal community acquired pneumonia (CAP) and IPD was assessed in a randomized, double-blind, placebo-controlled study (Community-Acquired Pneumonia Immunization Trial in Adults [CAPiTA]) conducted over four years in the Netherlands. A total of 84,496 participants 65 years of age and older received a single dose of either PREVNAR 13 or placebo in a 1:1 randomization; 42,240 participants were vaccinated with PREVNAR 13 and 42,256 participants were vaccinated with placebo. Chronic medical conditions (asthma, diabetes, heart, liver, and/or lung diseases) were reported in 42.3% of study participants at baseline.

The primary endpoint was the prevention of a first episode of confirmed VT-CAP (defined as the presence of ≥2 pre-specified clinical criteria, chest X-ray consistent with CAP, and positive VT-specific Urinary Antigen Detection assay or isolation of VT *S. pneumoniae* from blood or other sterile site). The secondary endpoints were the prevention of a first episode of 1) confirmed non-bacteremic/non-invasive (NB/NI) VT-CAP (an episode of VT-CAP for which the blood or sterile site cultures were negative for *S. pneumoniae*) and 2) VT-IPD (the presence of *S. pneumoniae* in a sterile site).

The per-protocol population was the primary population for analysis of all primary and secondary efficacy objectives. The mean duration of follow-up was 3.97 years. PREVNAR 13 demonstrated statistically significant vaccine efficacy (VE) in preventing first episodes of VT pneumococcal CAP, NB/NI VT pneumococcal CAP, and VT-IPD (Table 9).

Table 9. Vaccine Efficacy for the Primary and Secondary Endpoints of the CAPiTA Study

Efficacy endpoints	Total Number of Episodes	PREVNAR 13 N=42,240	Placebo N=42,256	VE (%)	95.2% CI	p value
		n	n			
VT pneumococcal CAP	139	49	90	45.6	21.8, 62.5	0.0006
NB/NI VT pneumococcal CAP	93	33	60	45	14.2, 65.3	0.0067
VT-IPD	35	7	28	75	41.1, 90.9	0.0005

Abbreviations: CAP = community-acquired pneumonia; N = number of participants; NB/NI = non-bacteremic/non-invasive; IPD = invasive pneumococcal disease; VE = vaccine efficacy; VT = vaccine-type.

PREVNAR 13 Immune Responses in Special Populations

HIV-infected adults 18 years of age and older

In HIV-infected adults free of active acquired immunodeficiency syndrome-related illness, and not previously vaccinated with a pneumococcal vaccine, 131 evaluable patients received three doses of PREVNAR 13 and subsequently a single dose of PPSV23. Vaccines were administered at 1 month intervals. Immune responses approximately 1 month after each dose of vaccine elicited antibody levels, measured by both immunoglobulin G (IgG) geometric mean concentrations (GMCs) and opsonophagocytic activity (OPA) geometric mean titers (GMTs), that were statistically significantly higher compared to levels prior to vaccination. After the second and third dose of PREVNAR 13, immune responses were similar to or higher than those after the first dose (Bhorat *et al.* 2015, AIDS 29:1345).

In HIV-infected adults free of active AIDS-related illness and previously vaccinated with PPSV23 administered at least 6 months prior to enrollment, 329 patients received three doses of PREVNAR 13: at enrollment, 6 and 12 months after the first dose. After the first vaccination, PREVNAR 13 elicited antibody levels measured by both IgG GMCs and OPA GMTs that were higher compared to levels prior to vaccination. After the second and third dose of PREVNAR 13, immune responses were comparable to or higher than those after the first dose. Subjects who received 2 or more previous doses of PPSV23 showed a similar immune response compared with subjects who received a single previous dose (Glesby *et al.* 2015, JID 212:18).

Hematopoietic stem cell transplant (HSCT)

In adults 18 years of age and older with an allogeneic HSCT with complete hematologic remission of underlying disease (or very good partial remission in the case of lymphoma and myeloma), 159 evaluable patients received three doses of PREVNAR 13 at intervals of at least 1 month between doses. The first dose was administered at 3 to 6 months after HSCT. A fourth booster dose of PREVNAR 13 was administered 6 months after the third dose, followed by a single dose of PPSV23 at 1 month after the fourth dose. PREVNAR 13 elicited increased antibody levels after each dose of PREVNAR 13. Approximately 1 month after vaccination, immune responses after the fourth dose of PREVNAR 13 were significantly increased for all serotypes compared with the third dose (Cordonnier *et al.* 2015, CID 61:313).

15 MICROBIOLOGY

No microbiological information is required for this drug product.

16 NON-CLINICAL TOXICOLOGY

General Toxicology:

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

Carcinogenicity:

Carcinogenic potential was not assessed, as carcinogenicity studies were not considered relevant to this vaccine.

Genotoxicity:

Genotoxic potential was not assessed, as genotoxicity studies were not considered relevant to this vaccine.

Reproductive and Developmental Toxicology:

In a fertility and developmental toxicity study, female rabbits were administered PREVNAR 20 by intramuscular injection twice prior to mating (17 days and 4 days prior to mating) and twice during gestation (Gestation Days 10 and 24), 0.5 mL/rabbit/occasion (a single human dose). No adverse effects on pre-weaning development were observed. There were no vaccine-related fetal malformations or variations.

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PREVNAR 20™

Pneumococcal 20-valent Conjugate Vaccine (Diphtheria CRM_{197} Protein)
Suspension for Intramuscular Injection

Read this carefully before you receive **PREVNAR 20**. This leaflet is a summary and will not tell you everything about this vaccine. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **PREVNAR 20**.

What is PREVNAR 20 used for?

PREVNAR 20 is a pneumococcal vaccine given to:

- Adults 18 years of age and older to prevent pneumococcal diseases such as: pneumonia (lung infection), bacteremic pneumonia (lung infection with bacteria in the blood stream), sepsis or bacteremia (bacteria in the blood stream) and meningitis (inflammation around the brain), caused by 20 types of the bacteria *Streptococcus pneumoniae*.

How does PREVNAR 20 work?

This vaccine works by helping the body to make its own antibodies, which protect you against these diseases. PREVNAR 20 provides protection against 20 types of *Streptococcus pneumoniae* bacteria.

What are the ingredients in PREVNAR 20?

Medicinal ingredients: One dose (0.5 mL) contains the following active substances linked to the non-toxic diphtheria (CRM_{197}) carrier protein:

- 2.2 micrograms of polysaccharide for serotypes 1, 3, 4, 5, 6A, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F and 33F
- 4.4 micrograms of polysaccharide for serotype 6B

Non-medicinal ingredients: aluminum phosphate, polysorbate 80, sodium chloride, succinic acid, water for injection.

PREVNAR 20 comes in the following dosage forms:

A white suspension for intramuscular injection, provided in a single-dose (0.5 mL), pre-filled syringe.

Do not use PREVNAR 20 if:

- you are allergic (hypersensitive) to the active substances or to any of the other ingredients in this vaccine, or to any other vaccine that contains diphtheria toxoid.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you receive PREVNAR 20. Talk about any health conditions or problems you may have, including if you:

- have any present or past medical problems after any dose of PREVNAR 20, PREVNAR 13 or PREVNAR, such as an allergic reaction or problems with breathing.

- have a severe illness or high fever. However, a mild fever or upper respiratory infection (for example having a cold) itself is not a reason to delay vaccination.
- have any bleeding problems or bruise easily.
- have a weakened immune system due to a medical condition or are on a medicine that affects your immune system. You may not get the full benefit from PREVNAR 20.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your healthcare professional for advice before receiving this vaccine.

Other warnings you should know about:

As with any vaccine, PREVNAR 20 will not protect all persons who are vaccinated.

PREVNAR 20 has no or negligible influence on the ability to drive and use machines. However, some of the side effects mentioned under "What are possible side effects from using PREVNAR 20" may temporarily affect the ability to drive or use machines.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Tell your healthcare professional if you have been given a pneumococcal vaccine before, or have recently received any other vaccine.

How PREVNAR 20 is given:

A healthcare professional will inject the recommended dose (0.5 mL) of the vaccine into your arm.

If you have any further questions on the use of PREVNAR 20, ask your healthcare professional.

Usual dose:

You should receive one injection (0.5 mL dose) of the vaccine.

Overdose:

Overdose with PREVNAR 20 is unlikely as it is supplied as a single-dose pre-filled syringe.

If you think you, or a person you are caring for, have received too much PREVNAR 20, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using PREVNAR 20?

Like all vaccines, PREVNAR 20 can cause side effects, although not everybody gets them.

The following side effects include those reported for PREVNAR 20 in adults:

Very common: may occur in more than 1 in 10 individuals
- Headache
- Joint/muscle pain
- Pain/tenderness at injection site
- Tiredness

Common: may occur in more than 1 in 100 and up to 1 in 10 individuals
- Swelling/redness at injection site
- Fever (38°C or higher)

Uncommon: may occur in more than 1 in 1000 and up to 1 in 100 individuals
- Allergic reaction including swelling, shortness of breath, wheezing,
- Diarrhea, nausea and vomiting
- Rash and swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- Itching/hives at the injection site
- Swollen glands in the neck, armpit or groin
- Chills

The following side effects were seen with PREVNAR 13 and may also be seen with PREVNAR 20:

- Severe allergic reaction, shock or cardiovascular collapse

These are not all the possible side effects you may have when receiving PREVNAR 20. If you experience any side effects not listed here, tell your healthcare professional.

Reporting Suspected Side Effects for Vaccines

For the general public: Should you experience a side effect following immunization, please report it to your healthcare professional.

Should you require information related to the management of the side effect, please contact your healthcare professional. The Public Health Agency of Canada, Health Canada and Pfizer Canada ULC cannot provide medical advice.

For healthcare professionals: If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (http://www.phac-aspc.gc.ca/im/aefi-essi-form-eng.php) and send it to your local Health Unit.

Storage:

Store in a refrigerator (2°C to 8 °C). PREVNAR 20 should be used as soon as possible after being removed from refrigeration.

Do not freeze. Discard if vaccine has been frozen.

Store syringes in the refrigerator horizontally (laying flat on shelf) to minimise the re-dispersion time.

Keep out of reach and sight of children.

Do not use this vaccine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.

Ask your pharmacist how to throw away any unused vaccine.

If you want more information about PREVNAR 20:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html; the manufacturer's website [pfizer.ca], or by calling 1-800-463-6001 (Pfizer Medical Information).

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