Product Monograph

Including Patient Medication Information

CAPVAXIVE®

Pneumococcal 21-valent Conjugate Vaccine

Solution for injection

Active immunizing agent (pneumococcal vaccines; ATC code: J07AL02)

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Recent Major Label Changes

1 Indications, 1.1 Pediatric	2026-09
4 Dose and Administration, 4.2 Recommended Dose and Dosage Adjustment	2026-09
7 Warnings and Precautions, 7.1.3 Pediatrics	2026-09

Table of Contents

Certain sections (as indicated in section 2.1. of the PM Guidance) or subsections that are not applicable at the time of the preparation of the most recent authorized product monograph are not listed.

Recent Major Label Changes **2**

Table of Contents **2**

Part 1: Healthcare Professional Information **4**

1. Indications **4**

1.1. Pediatrics 4

1.2. Geriatrics 4

2. Contraindications **4**

4. Dosage and Administration **4**

4.2. Recommended Dose and Dosage Adjustment 4

4.4. Administration 5

4.5. Missed Dose 5

5. Overdose **5**

6. Dosage Forms, Strengths, Composition, and Packaging **5**

7. Warnings and Precautions **6**

General 6

Driving and Operating Machinery 6

Hematologic 6

Immune 6

7.1. Special Populations 7

7.1.1. Pregnancy 7

7.1.2. Breastfeeding 7

7.1.3. Pediatrics 7

7.1.4. Geriatrics 7
8. Adverse Reactions 7
8.1. Adverse Reaction Overview 7
8.2. Clinical Trial Adverse Reactions 8
8.2.1. Clinical Trial Adverse Reactions – Pediatrics 15
8.3. Less Common Clinical Trial Adverse Reactions 17
8.3.1. Less Common Clinical Trial Adverse Reactions – Pediatrics 17
8.5. Post-Market Adverse Reactions 17
9. Drug Interactions 17
9.4. Drug-Drug Interactions 17
10. Clinical Pharmacology 17
10.1. Mechanism of Action 18
11. Storage, Stability, and Disposal 18
12. Special Handling Instructions 18
Part 2: Scientific Information 19
13. Pharmaceutical Information 19
14. Clinical Trials 20
14.1. Clinical Trials by Indication 20
Adults 18 years of Age and Older 20
Children and Adolescents 2 to Less Than 18 Years of Age at Increased Risk for Pneumococcal Disease due to Certain Medical Conditions 29
15. Microbiology 31
16. Non-Clinical Toxicology 32
Patient Medication Information 33

Part 1: Healthcare Professional Information

1. Indications

CAPVAXIVE® (Pneumococcal 21-valent Conjugate Vaccine) is indicated for active immunization for the prevention of invasive pneumococcal disease (including sepsis, meningitis, bacteremic pneumonia, pleural empyema and bacteremia) caused by *Streptococcus pneumoniae* serotypes (3, 6A, 6C, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B) in:

- adults 18 years of age and older
- children and adolescents 2 to less than 18 years of age who are at increased risk for pneumococcal disease and who have previously completed a primary pneumococcal vaccination regimen.

1.1. Pediatrics

Children less than 2 years old: The safety and effectiveness of CAPVAXIVE® in individuals younger than 2 years of age have not yet been established.

Children and adolescents 2 to less than 18 years old: Based on the data submitted and reviewed by Health Canada, the safety profile and immune responses of CAPVAXIVE® in children and adolescents who are at increased risk for pneumococcal disease and who have previously completed a primary pneumococcal vaccination regimen have been established. Therefore, Health Canada has authorized an indication for pediatric use in individuals 2 to less than 18 years of age who are at increased risk for pneumococcal disease and who have previously completed a primary pneumococcal vaccination regimen. (see 1. Indications, 8.2.1 Clinical Trial Adverse Reactions – Pediatrics, 14 Clinical Trials).

1.2. Geriatrics

CAPVAXIVE® has been studied in individuals 65 years of age and older (see 7.1.4 Geriatrics, 14 Clinical Trials).

2. Contraindications

CAPVAXIVE® is contraindicated in individuals with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine including diphtheria toxoid (see 6 Dosage Forms, Strengths, Composition and Packaging).

4. Dosage and Administration

4.2. Recommended Dose and Dosage Adjustment

Administer a single 0.5 mL dose of CAPVAXIVE® intramuscularly.

Prior vaccination with another Pneumococcal Vaccine
A single dose of CAPVAXIVE® can be given to adults who have been vaccinated with other pneumococcal vaccines at least 1 year prior.

A single dose of CAPVAXIVE® can be given to children and adolescents 2 to less than 18 years of age who are at increased risk for pneumococcal disease and who have previously completed a primary pneumococcal vaccination regimen.

4.4. Administration

For intramuscular injection only. Do not inject intravascularly.

Instructions for use:
CAPVAXIVE® should not be diluted or mixed with other vaccines. The full recommended dose of the vaccine should be used.

When CAPVAXIVE® is administered at the same time as another injectable vaccine(s), the vaccines should always be given at different injection sites (see 9.4 Drug-Drug Interactions)**.**

The vaccine is a colorless, clear to opalescent solution. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. This product should not be used if particulate matter or discoloration is found.

The prefilled syringe is for single use only and should not be used for more than one individual. Attach a needle by twisting in a clockwise direction until the needle fits securely on the syringe. Inject the entire contents of the syringe.

4.5. Missed Dose

Not Applicable. This vaccine is administered as a single dose.

5. Overdose

There have been no reports of administration of higher than the recommended dose of CAPVAXIVE®.

For the most recent information in the management of a suspected drug overdose, contact your regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669).

6. Dosage Forms, Strengths, Composition, and Packaging

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.

CAPVAXIVE® is a solution for injection available in 0.5 mL single dose prefilled syringes.

The vaccine is a colorless, clear to opalescent solution.

Available in 1 or 10 prefilled syringes packages.

The tip cap and plunger stopper are latex free.

Table 1: Dosage Forms, Strengths, and Composition

Route of Administration	Dosage Form / Strength/Composition	Non-medicinal Ingredients
Intramuscular injection	Solution for injection. Each 0.5 mL dose contains a total of 84 mcg of pneumococcal polysaccharide antigen (4 mcg each of polysaccharide serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, deOAc15B, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B) conjugated to approximately 65 mcg of CRM197 carrier protein.	Each 0.5 mL dose contains 1.55 mg L-histidine, 0.50 mg of polysorbate 20, 4.49 mg sodium chloride, and water for injection. CAPVAXIVE® does not contain any preservatives.

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 CAPVAXIVE® 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.

CAPVAXIVE® will only protect against *Streptococcus pneumoniae* serotypes included in the indication, and will not protect against other microorganisms that cause invasive disease or pneumonia.

As with any vaccine, CAPVAXIVE® may not protect all individuals receiving the vaccine from invasive pneumococcal disease.

Driving and Operating Machinery

CAPVAXIVE® has no or negligible influence on the ability to drive and 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

Based on experience with pneumococcal vaccines, immunocompromised individuals, including those receiving immunosuppressive therapy, may have a reduced immune response to CAPVAXIVE®.

7.1. Special Populations

7.1.1. Pregnancy

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/foetal development, parturition or post-natal development (see 16 Non-Clinical Toxicology).

Safety during pregnancy has not been established in humans.

7.1.2. Breastfeeding

Safety during lactation has not been established in humans. It is not known whether this vaccine is excreted in human milk.

7.1.3. Pediatrics

The safety and effectiveness of CAPVAXIVE® in children younger than 2 years of age have not been established. Overall, there were no clinically meaningful differences in the safety profile or immune responses observed in children and adolescents 2 to less than 18 years of age who are at increased risk for pneumococcal disease and who have previously completed a primary pneumococcal vaccination regimen, when compared to adults 18 years of age and older (see 8 Adverse Reactions and 14 Clinical Trials).

7.1.4. Geriatrics

Across the Phase 3 clinical studies, approximately 34% of individuals were 65 years of age and older. Of the 4,556 individuals who received CAPVAXIVE®, 1,487 (32.6%) were 65 years and older, and 339 (7.4%) were 75 years and older. Overall, there were no clinically meaningful differences in the safety profile or immune responses observed in individuals 65 to 74 years and 75 years of age and older when compared to individuals less than 65 years of age (see 8.2 Clinical Trial Adverse Reactions and 14 Clinical Trials).

8. Adverse Reactions

8.1. Adverse Reaction Overview

The safety of CAPVAXIVE® in adults was assessed in four clinical studies in approximately 6,500 adults ≥ 18 years of age (V116-003, V116-004, V116-005 and V116-006). Across all 4 studies, approximately 4,500 adults received CAPVAXIVE®, approximately 2,000 adults received an active comparator

The most commonly reported (>10%) solicited adverse reactions in individuals 18 to 49 years of age following vaccination with CAPVAXIVE® were: injection site pain (73.1%), fatigue (36.0%), headache (27.5%), myalgia (16.4%), injection site erythema (13.8%), and injection site swelling (13.3%).

The most commonly reported (>10%) solicited adverse reactions in individuals 50 years of age and older who received CAPVAXIVE® were: injection site pain (41.2%), fatigue (19.7%), and headache (11.0%).

Across the Phase 3 studies in individuals 18 years of age and older, the majority of local and systemic solicited adverse reactions were mild (based on intensity or size) and of short duration (≤3 days); severe events (defined as an event that prevents normal daily activity or size >10 cm) occurred in ≤1.0% of adults (see 8.2 Clinical Trial Adverse Reactions and **Table 2**, **Table 3** and **Table 4**).

The safety of CAPVAXIVE® was also assessed in populations at increased risk for invasive pneumococcal disease (IPD) (study V116-007 and study V116-008).

The safety of CAPVAXIVE® was assessed in individuals 2 to less than 18 years of age with one or more prespecified chronic medical conditions (diabetes mellitus, chronic heart disease, chronic kidney disease, chronic liver disease, chronic lung disease) known to increase the risk of pneumococcal disease and who have previously completed a primary pneumococcal vaccine regimen (Study V116-013). In Study V116-013, 527 individuals received CAPVAXIVE® and 347 individuals received active comparator vaccine.

The most commonly reported (>10%) solicited adverse reactions in individuals 2 to less than 18 years of who are at increased risk for pneumococcal disease were injection-site pain (67.7%), injection-site erythema (24.3%), fatigue (20.1%), injection-site swelling (18.8%), headache (17.1%), malaise (13.3%), and irritability (11.6%).

8.2. Clinical Trial Adverse Reactions

Clinical trials are conducted under very specific conditions. Therefore, the frequencies of adverse reactions observed in the clinical trials may not reflect frequencies observed in clinical practice and should not be compared to frequencies reported in clinical trials of another drug.

The safety of CAPVAXIVE® in adults was assessed in four clinical studies (V116-003, V116-004, V116-005, and V116-006) conducted across the Americas, Europe, and Asia Pacific, which included approximately 6,500 adults ranging in age from 18 to 97 years of age. Each study included adults with stable underlying medical conditions (see 14 Clinical Trials). Across all 4 studies, approximately 4,500 participants received CAPVAXIVE®, and approximately 2,000 adults received an active comparator.

The safety of CAPVAXIVE® in adults was assessed in two additional studies (V116-007 and V116-008) which enrolled populations at increased risk for invasive pneumococcal disease.

Study V116-007 was conducted across the Americas, Africa, Europe and Asia Pacific among adults ≥18 years of age living with well-managed HIV infection (see 14 Clinical Trials). In this study, 155 adults received CAPVAXIVE® (PCV21) and 157 adults received VAXNEUVANCE® (PCV15) then PNEUMOVAX® 23 (PPSV23) eight weeks later. Among all vaccinated participants, there were 74.7% with CD4+ T-cell count ≥500 cells/µL at screening, and 83.0% with undetectable HIV viral load (<20 copies/mL).

Study V116-008 was conducted across the Americas, Europe, and Asia Pacific among adults 18 to 64 years of age with one or more chronic medical conditions associated with higher risk of IPD (see 14 Clinical Trials). In this study, 386 adults received CAPVAXIVE® and 130 adults received VAXNEUVANCE® then PNEUMOVAX® 23 eight weeks later. Among all vaccinated participants, there were 37.6% with diabetes mellitus only, 19.2% with chronic lung disease only, 16.3% with chronic heart disease only, 6.6% with chronic liver disease only, 4.5% with chronic kidney disease only, and 15.9 % with ≥2 increased-risk conditions.

In all studies, safety was evaluated using an electronic Vaccination Report Card for 30 days postvaccination. Injection site adverse events, systemic adverse events, and body temperature were solicited Day 1 through Day 5 postvaccination. Unsolicited adverse events were reported Day 1 through Day 30 postvaccination. Serious adverse events (SAEs) were reported through 6 months postvaccination with CAPVAXIVE® in all studies.

Solicited Adverse Events

Pneumococcal Vaccine Naïve Adults 18 years of Age and Older

In study V116-003 [NCT05425732], individuals 18 years of age and older who had not previously received a pneumococcal vaccine were enrolled and randomized to receive a single dose of CAPVAXIVE® or Prevnar*20.

A comparable proportion of individuals within each age group (18 to 49 and 50 years of age and older) who received CAPVAXIVE® or Prevnar*20, reported solicited adverse events.
The percentage of individuals with solicited adverse reactions that occurred within 5 days following administration of CAPVAXIVE® or Prevnar*20 in studyV116-003 is shown in **Table 2**. Pneumococcal vaccine naïve adults 50 years of age and older reported fewer solicited adverse events than adults 18 to 49 years of age, regardless of vaccination group.

Table 2*:* Individuals with Solicited Local and Systemic Adverse Events Within 5 days Postvaccination in Pneumococcal Vaccine-Naïve Adults 18-49 Years of Age and ≥50 Years of Age – V116-003

		18-49 Years of Age		≥50 Years of Age	
		CAPVAXIVE® n (%)	Prevnar*20 n (%)	CAPVAXIVE® n (%)	Prevnar*20 n (%)
Individuals in population[a]		200	100	1177	1175
One or more solicited adverse events		161 (80.5)	78 (78.0)	600 (51.0)	708 (60.3)
No solicited adverse events		39 (19.5)	22 (22.0)	577 (49.0)	467 (39.7)
Local adverse events[†]	**Severity**				
Pain	Any	143 (71.5)	74 (74.0)	464 (39.4)	607 (51.7)
	Mild	95 (47.5)	49 (49.0)	361 (30.7)	504 (42.9)
	Moderate	46 (23.0)	25 (25.0)	102 (8.7)	102 (8.7)
	Severe	2 (1.0)	0 (0.0)	1 (0.1)	1 (0.1)
Erythema	Any	31 (15.5)	13 (13.0)	64 (5.4) [‡]	74 (6.3) [‡]
	Mild	23 (11.5)	10 (10.0)	51 (4.3)	59 (5.0)
	Moderate	7 (3.5)	3 (3.0)	10 (0.8)	12 (1.0)
	Severe	1 (0.5)	0 (0.0)	2 (0.2)	2 (0.2)
Swelling	Any	28 (14.0)	14 (14.0)	71 (6.0)	98 (8.3)
	Mild	20 (10.0)	9 (9.0)	53 (4.5)	79 (6.7)

		18-49 Years of Age		≥50 Years of Age	
		CAPVAXIVE® n (%)	Prevnar*20 n (%)	CAPVAXIVE® n (%)	Prevnar*20 n (%)
Individuals in population[a]		200	100	1177	1175
One or more solicited adverse events		161 (80.5)	78 (78.0)	600 (51.0)	708 (60.3)
No solicited adverse events		39 (19.5)	22 (22.0)	577 (49.0)	467 (39.7)
	Moderate	7 (3.5)	5 (5.0)	15 (1.3)	17 (1.4)
	Severe	1 (0.5)	0 (0.0)	3 (0.3)	2 (0.2)
Systemic adverse events[†]	**Severity**				
Fatigue	Any	81 (40.5)	34 (34.0)	237 (20.1)	230 (19.6)
	Mild	50 (25.0)	21 (21.0)	167 (14.2)	153 (13.0)
	Moderate	29 (14.5)	11 (11.0)	70 (5.9)	72 (6.1)
	Severe	2 (1.0)	2 (2.0)	0 (0.0)	5 (0.4)
Headache	Any	59 (29.5)	24 (24.0)	135 (11.5)	152 (12.9)
	Mild	44 (22.0)	17 (17.0)	102 (8.7)	106 (9.0)
	Moderate	14 (7.0)	7 (7.0)	33 (2.8)	45 (3.8)
	Severe	1 (0.5)	0 (0.0)	0 (0.0)	1 (0.10)
Myalgia	Any	33 (16.5)	14 (14.0)	70 (5.9)	79 (6.7)
	Mild	15 (7.5)	9 (9.0)	40 (3.4)	42 (3.6)
	Moderate	15 (7.5)	4 (4.0)	30 (2.5)	36 (3.1)
	Severe	3 (1.5)	1 (1.0)	0 (0.0)	1 (0.1)
Pyrexia [§]	≥38.0°C	7 (3.5)	1 (1.0)	15 (1.3)	15 (1.3)
	≥38.0°C to <38.5°C	3 (1.5)	0 (0.0)	7 (0.6)	7 (0.6)
	≥38.5°C to <39.0°C	2 (1.0)	0 (0.0)	6 (0.5)	5 (0.4)
	≥39.0°C	2 (1.0)	1 (1.0)	2 (0.2)	3 (0.3)

[a] Every individual is counted a single time for each applicable row and column.
[†] Injection-site erythema, injection-site pain, injection-site swelling, fatigue, headache, and myalgia were solicited from Day 1 through Day 5 postvaccination.
[‡] Includes one individual with an event of unknown intensity.
[§] Pyrexia was defined as temperature ≥38.0°C solicited from Day 1 through Day 5 postvaccination. Percentages are based on the number of individuals with temperature data.
Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.

In study V116-004 [NCT05464420], individuals 18 to 49 years of age who had not previously received a pneumococcal vaccine were enrolled and randomized to receive a single dose of CAPVAXIVE® or PNEUMOVAX® 23.

A comparable proportion of individuals 18 to 49 years of age who received CAPVAXIVE® or PNEUMOVAX® 23 reported solicited adverse events. The percentage of participants with solicited adverse reactions that occurred within 5 days following administration of CAPVAXIVE® or PNEUMOVAX® 23 in study V116-004 is shown in **Table 3**.

Table 3: Individuals with Solicited Local and Systemic Adverse Events Within 5 Days Postvaccination in Pneumococcal Vaccine-Naïve Adults 18-49 Years of Age – V116-004

		CAPVAXIVE® n (%)	PNEUMOVAX® 23 n (%)
Individuals in population[a]		1,616	541
One or more solicited adverse events		1,263 (78.2)	387 (71.5)
No solicited adverse events		353 (21.8)	154 (28.5)
Local adverse events[†]	**Severity**		
Pain	Any	1,184 (73.3)	328 (60.6)
	Mild	759 (47.0)	234 (43.3)
	Moderate	395 (24.4)	86 (15.9)
	Severe	30 (1.9)	8 (1.5)
Erythema	Any	219 (13.6)	41 (7.6)
	Mild	143 (8.8)	30 (5.5)
	Moderate	57 (3.5)	8 (1.5)
	Severe	19 (1.2)	3 (0.6)
Swelling	Any	213 (13.2)	41 (7.6)
	Mild	148 (9.2)	29 (5.4)
	Moderate	55 (3.4)	10 (1.8)
	Severe	10 (0.6)	2 (0.4)
Systemic adverse events[†]	**Severity**		
Fatigue	Any	573 (35.5)	184 (34.0)
	Mild	338 (20.9)	119 (22.0)
	Moderate	201 (12.4)	60 (11.1)
	Severe	34 (2.1)	5 (0.9)
Headache	Any	440 (27.2)	116 (21.4)
	Mild	275 (17.0)	70 (12.9)
	Moderate	151 (9.3)	43 (7.9)
	Severe	14 (0.9)	3 (0.6)
Myalgia	Any	264 (16.3)	47 (8.7)
	Mild	146 (9.0)	33 (6.1)
	Moderate	103 (6.4)	12 (2.2)
	Severe	15 (0.9)	2 (0.4)
Pyrexia[‡]	≥38.0°C	48 (3.0)	12 (2.2)
	≥38.0°C to <38.5°C	31 (1.9)	4 (0.7)
	≥38.5°C to <39.0°C	11 (0.7)	2 (0.4)
	≥39.0°C	6 (0.4)	6 (1.1)

[a] Every individual is counted a single time for each applicable row and column.
[†] Injection-site erythema, injection-site pain, injection-site swelling, fatigue, headache, and myalgia were solicited from Day 1 through Day 5 postvaccination.
[‡] Pyrexia was defined as temperature ≥38.0°C solicited from Day 1 through Day 5 postvaccination. Percentages are based on the number of individuals with temperature data.
Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.

Adults 50 Years of Age and Older Who Previously Received Pneumococcal Vaccines

Study V116-006 [NCT05420961] enrolled individuals 50 years of age and older who had previously received a pneumococcal vaccine at least 1 year prior to enrollment.

Adults who previously received PNEUMOVAX® 23 (double-blind; cohort 1) were randomized to receive a single dose of either CAPVAXIVE® or VAXNEUVANCE®.

Adults who previously received Prevnar*13 (double-blind; cohort 2) were randomized to receive a single dose of either CAPVAXIVE® or PNEUMOVAX® 23.

Adults who previously received other prior pneumococcal vaccines (Prevnar*13 + PNEUMOVAX® 23, VAXNEUVANCE® + PNEUMOVAX® 23, PNEUMOVAX® 23 + Prevnar*13, or VAXNEUVANCE®) were allocated to receive a single dose of CAPVAXIVE® (open-label; cohort 3).

Within Cohort 1 and Cohort 2, a comparable proportion of pneumococcal vaccine experienced individuals who received CAPVAXIVE® or active comparator reported solicited adverse events, regardless of prior pneumococcal vaccines received.

The percentage of participants with solicited adverse reactions that occurred within 5 days following administration of CAPVAXIVE® or a comparator in study V116-006 is shown in **Table 4**.

Across the 3 cohorts, comparable proportions of individuals who received CAPVAXIVE® reported solicited adverse events, regardless of prior pneumococcal vaccines received.

Table 4: Individuals with Solicited Local and Systemic Adverse Events Within 5 Days Postvaccination in Adults ≥50 Years of Age with Prior Pneumococcal Vaccination – V116-006

		Cohort 1[a]		Cohort 2[†]		Cohort 3[‡]
		CAPVAXIVE® n (%)	VAXNEUVANCE® n (%)	CAPVAXIVE® n (%)	PNEUMOVAX® 23 n (%)	CAPVAXIVE® n (%)
Individuals in population[§]		230	117	174	85	105
One or more solicited adverse events		107 (46.5)	65 (55.6)	86 (49.4)	52 (61.2)	51 (48.6)
No solicited adverse events		123 (53.5)	52 (44.4)	88 (50.6)	33 (38.8)	54 (51.4)
Local adverse events[¶]	**Severity**					
Pain	Any	82 (35.7)	51 (43.6)	72 (41.4)	40 (47.1)	46 (43.8)
	Mild	65 (28.3)	43 (36.8)	52 (29.9)	30 (35.3)	37 (35.2)
	Moderate	16 (7.0)	8 (6.8)	20 (11.5)	10 (11.8)	9 (8.6)
	Severe	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Erythema	Any	17 (7.4)	9 (7.7)	13 (7.5)	8 (9.4)	8 (7.6)
	Mild	10 (4.3)	6 (5.1)	5 (2.9)	2 (2.4)	4 (3.8)
	Moderate	5 (2.2)	2 (1.7)	6 (3.4)	6 (7.1)	3 (2.9)
	Severe	2 (0.9)	1 (0.9)	2 (1.1)	0 (0.0)	1 (1.0)
Swelling	Any	19 (8.3)	10 (8.5)	8 (4.6)	14 (16.5)	11 (10.5)
	Mild	15 (6.5)	9 (7.7)	6 (3.4)	7 (8.2)	6 (5.7)
	Moderate	4 (1.7)	1 (0.9)	2 (1.1)	7 (8.2)	4 (3.8)

		Cohort 1[a]		Cohort 2[†]		Cohort 3[‡]
		CAPVAXIVE® n (%)	VAXNEUVANCE® n (%)	CAPVAXIVE® n (%)	PNEUMOVAX® 23 n (%)	CAPVAXIVE® n (%)
	Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
Systemic adverse events[¶]	**Severity**					
Fatigue	Any	33 (14.3)	20 (17.1)	33 (19.0)	11 (12.9)	23 (21.9)
	Mild	25 (10.9)	11 (9.4)	24 (13.8)	6 (7.1)	19 (18.1)
	Moderate	8 (3.5)	9 (7.7)	8 (4.6)	5 (5.9)	4 (3.8)
	Severe	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Headache	Any	16 (7.0)	11 (9.4)	18 (10.3)	10 (11.8)	9 (8.6)
	Mild	10 (4.3)	9 (7.7)	10 (5.7)	7 (8.2)	9 (8.6)
	Moderate	5 (2.2)	2 (1.7)	8 (4.6)	3 (3.5)	0 (0.0)
	Severe	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Myalgia	Any	17 (7.4)	3 (2.6)	17 (9.8)	8 (9.4)	9 (8.6)
	Mild	9 (3.9)	2 (1.7)	7 (4.0)	4 (4.7)	7 (6.7)
	Moderate	8 (3.5)	1 (0.9)	9 (5.2)	4 (4.7)	2 (1.9)
	Severe	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Pyrexia[#]	≥38.0°C	4 (1.7)	3 (2.6)	5 (2.9)	1 (1.2)	0 (0.0)
	≥38.0°C to <38.5°C	2 (0.9)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
	≥38.5°C to <39.0°C	2 (0.9)	2 (1.7)	2 (1.1)	1 (1.2)	0 (0.0)
	≥39.0°C	0 (0.0)	1 (0.9)	2 (1.1)	0 (0.0)	0 (0.0)

[a] Cohort 1 prior vaccination with PNEUMOVAX® 23
[†] Cohort 2 prior vaccination with Prevnar*13
[‡] Cohort 3 prior vaccination with Prevnar*13+PNEUMOVAX® 23 (n=45), or VAXNEUVANCE®+PNEUMOVAX® 23 (n=5), or PNEUMOVAX® 23+Prevnar*13 (n=54), or VAXNEUVANCE® (n=1) or Prevnar*20 (n=0)
[§] Every individual is counted a single time for each applicable row and for each column.
[¶] Injection-site erythema, injection-site pain, injection-site swelling, fatigue, headache, and myalgia were solicited from Day 1 through Day 5 postvaccination.
[#] Pyrexia was defined as temperature ≥38.0°C solicited from Day 1 through Day 5 postvaccination. Percentages are based on the number of individuals with temperature data.
Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.

Safety with Concomitant Influenza Vaccine Administration in Adults
In study V116-005 [NCT05526716], the safety profile of CAPVAXIVE® when administered concomitantly with quadrivalent inactivated influenza vaccine (QIV) was generally consistent with the safety profile of CAPVAXIVE® in adults 50 years of age and older.

Unsolicited Adverse Events in Adults
Across the Phase 3 clinical studies, there were no notable patterns or imbalances between vaccine groups for unsolicited adverse events assessed to be related to study vaccine by the investigator that occurred within 1-month postvaccination.

Serious Adverse Events in Adults
Across the Phase 3 clinical studies, the proportion of individuals reporting 1 or more SAEs within 6 months postvaccination was comparable between individuals vaccinated with CAPVAXIVE® (1.4%), and individuals vaccinated with an active comparator (2.0%). There were no notable patterns or imbalances

between vaccine groups for SAEs. There were 2 SAEs (0.05%; bronchospasm, cellulitis) assessed by the investigator to be related to CAPVAXIVE®.

Additional information in special populations

Adults ≥18 Years of Age Living with HIV infection

In study V116-007 [NCT05393037] among adults living with well-managed HIV infection, the safety profile of CAPVAXIVE® was generally comparable to the safety profile of VAXNEUVANCE® followed by PNEUMOVAX® 23 given eight weeks later. Following vaccination with CAPVAXIVE®, the most frequently reported (>10%) solicited adverse reactions were: injection-site pain (48.4%), fatigue (21.3%), and headache (16.8%). The percentage of individuals with solicited adverse reactions that occurred within 5 days following administration of CAPVAXIVE® followed by placebo or VAXNEUVANCE® followed by PNEUMOVAX® 23 in study V116-007 is shown in **Table 5.**

Table 5*:* Individuals with Solicited Local and Systemic Adverse Events Within 5 Days Postvaccination in Pneumococcal vaccine-naïve or pneumococcal vaccine-experienced adults ≥18 years of age living with HIV – V116-007

	CAPVAXIVE® followed by Placebo eight weeks later				VAXNEUVANCE® followed by PNEUMOVAX® 23 eight weeks later			
	CAPVAXIVE®		Placebo		VAXNEUVANCE®		PNEUMOVAX® 23	
	n	(%)	n	(%)	n	(%)	n	(%)
Individuals in population[a]	**155**		**153**		**155**		**151**	
with one or more solicited adverse events	87	(56.1)	44	(28.8)	103	(66.5)	110	(72.8)
with no solicited adverse events	68	(43.9)	109	(71.2)	52	(33.5)	41	(27.2)
Local adverse events[†]	**75**	**(48.4)**	**19**	**(12.4)**	**95**	**(61.3)**	**107**	**(70.9)**
Injection site erythema	4	(2.6)	4	(2.6)	4	(2.6)	15	(9.9)
Injection site pain	75	(48.4)	18	(11.8)	93	(60.0)	106	(70.2)
Injection site swelling	9	(5.8)	4	(2.6)	13	(8.4)	23	(15.2)
Systemic adverse events[†]	**49**	**(31.6)**	**35**	**(22.9)**	**45**	**(29.0)**	**45**	**(29.8)**
Fatigue	33	(21.3)	23	(15.0)	32	(20.6)	35	(23.2)
Headache	26	(16.8)	15	(9.8)	21	(13.5)	13	(8.6)
Myalgia	15	(9.7)	6	(3.9)	12	(7.7)	16	(10.6)
Pyrexia[‡]	2	(1.3)	1	(0.7)	3	(1.9)	2	(1.3)

[a] Every individual is counted a single time for each applicable row and column.

[†] Injection site erythema, injection site pain, injection site swelling, fatigue, headache, and myalgia were solicited from Day 1 through Day 5 following each vaccination.

[‡] Pyrexia was defined as maximum temperature ≥ 100.4 °F (38.0 °C) solicited from Day 1 through Day 5 following each vaccination.

The proportion of individuals with SAEs were comparable between sequential regimens, and none were assessed by the investigator to be related to CAPVAXIVE® (including one death at Day 128 post-vaccination assessed as unrelated).

Adults 18 to 64 Years of Age with Chronic Medical Conditions

In study V116-008 [NCT05696080] among adults with one or more chronic medical conditions associated with increased risk of invasive pneumococcal disease, the safety profile of CAPVAXIVE® was generally comparable to VAXNEUVANCE® followed by PNEUMOVAX® 23 given eight weeks later. Following vaccination with CAPVAXIVE®, the most frequently reported (>10%) solicited adverse reactions were: injection-site pain (49.5%), fatigue (24.6%), and headache (15.8%). The percentage of individuals with solicited adverse reactions that occurred within 5 days following administration of CAPVAXIVE® followed by placebo or VAXNEUVANCE® followed by PNEUMOVAX® 23 in study V116-008 is shown in **Table 6.**

Table 6*:* Individuals With Solicited Local and Systemic Adverse Events Within 5 Days Postvaccination In Pneumococcal vaccine-naïve adults 18 to 64 years of age with increased risk of invasive pneumococcal disease – V116-008

	CAPVAXIVE® followed by Placebo eight weeks later				**VAXNEUVANCE® followed by PNEUMOVAX® 23 eight weeks later**			
	CAPVAXIVE®		**Placebo**		**VAXNEUVANCE®**		**PNEUMOVAX® 23**	
	n	(%)	n	(%)	n	(%)	n	(%)
Individuals in population[a]	**386**		**374**		**130**		**128**	
with one or more solicited adverse events	226	(58.5)	93	(24.9)	92	(70.8)	104	(**81.3**)
with no solicited adverse events	160	(41.5)	281	(75.1)	38	(29.2)	24	(18.8)
Local adverse events[†]	**195**	**(50.5)**	**36**	**(9.6)**	**83**	**(63.8)**	**99**	**(77.3)**
Injection site erythema	27	(7.0)	10	(2.7)	5	(3.8)	30	(23.4)
Injection site pain	191	(49.5)	31	(8.3)	82	(63.1)	93	(72.7)
Injection site swelling	25	(6.5)	10	(2.7)	10	(7.7)	45	(35.2)
Systemic adverse events[†]	**127**	**(32.9)**	**77**	**(20.6)**	**40**	**(30.8)**	**55**	**(43.0)**
Fatigue	95	(24.6)	54	(14.4)	32	(24.6)	42	(32.8)
Headache	61	(15.8)	39	(10.4)	16	(12.3)	23	(18.0)
Myalgia	31	(8.0)	17	(4.5)	7	(5.4)	15	(11.7)
Pyrexia[‡]	7	(1.8)	7	(1.9)	0	(0.0)	6	(4.7)

[a] Every individual is counted a single time for each applicable row and column.

[†] Injection site erythema, injection site pain, injection site swelling, fatigue, headache, and myalgia were solicited from Day 1 through Day 5 following each vaccination.

[‡] Pyrexia was defined as maximum temperature ≥ 100.4 °F (38.0 °C) solicited from Day 1 through Day 5 following each vaccination.

The proportion of individuals with SAEs were comparable between sequential regimens, and none were assessed by the investigator to be related to CAPVAXIVE®.

8.2.1. Clinical Trial Adverse Reactions – Pediatrics

Study V116-013 [NCT06177912] was conducted to evaluate CAPVAXIVE® in children and adolescents 2 to less than 18 years of age with one or more prespecified chronic medical conditions known to increase the risk of pneumococcal disease and who have previously completed a primary pneumococcal vaccine regimen. The safety profile of CAPVAXIVE® was generally comparable to PNEUMOVAX® 23 (**Table 7**). Following vaccination with CAPVAXIVE®, the most frequently reported (>10%) solicited adverse reactions were: injection-site pain (67.7%), injection-site erythema (24.3%), fatigue (20.1%), injection-site swelling (18.8%), headache (17.1%), malaise (13.3%), and irritability (11.6%). There were no notable patterns or imbalances between vaccine groups for unsolicited adverse

events assessed to be related to CAPVAXIVE® vaccine by the investigator that occurred within 1-month postvaccination. The proportion of individuals with SAEs were comparable between vaccine groups, and one (0.2%; syncope) was assessed by the investigator to be related to CAPVAXIVE®.

Table 7: Individuals with Solicited Local and Systemic Adverse Events Within 5 Days Postvaccination in Children and Adolescents 2 to Less Than 18 Years of Age with Increased Risk of Pneumococcal Disease – V116-013

	CAPVAXIVE® **n (%)**	**PNEUMOVAX® 23** **n (%)**
Individuals in population [a]	527	347
One or more solicited adverse events	405 (76.9)	233 (67.1)
No solicited adverse events	122 (23.1)	114 (32.9)
Local adverse event†		
Erythema	128 (24.3)	57 (16.4)
Pain	357 (67.7)	189 (54.5)
Swelling	99 (18.8)	63 (18.2)
Systemic adverse event†		
Arthralgia	23 (4.4)	19 (5.5)
Fatigue	106 (20.1)	73 (21.0)
Headache	90 (17.1)	53 (15.3)
Irritability	61 (11.6)	38 (11.0)
Malaise	70 (13.3)	32 (9.2)
Myalgia	33 (6.3)	18 (5.2)
Somnolence	50 (9.5)	32 (9.2)
Urticaria	14 (2.7)	6 (1.7)
Pyrexia‡		
≥38.0°C (100.4°F) to <38.5°C (101.3°F)	15 (2.9)	8 (2.3)
≥38.5°C (101.3°F) to <39.0°C (102.2°F)	9 (1.7)	13 (3.8)
≥39.0°C (102.2°F)	4 (0.8)	1 (0.3)

[a] Every individual is counted a single time for each applicable row and column.

† Injection-site erythema, injection-site pain, injection-site swelling, arthralgia, fatigue, headache, irritability, malaise, myalgia, somnolence, and urticaria were solicited from Day 1 through Day 5 postvaccination.

‡ Pyrexia was defined as temperature ≥38.0°C (100.4°F) solicited from Day 1 through Day 5 postvaccination. Percentages are based on the number of individuals with temperature data.

8.3. Less Common Clinical Trial Adverse Reactions

No other adverse reactions not listed in the other tables were reported in clinical trials with frequency of ≥1/100.

The list below includes the less common adverse reactions reported in clinical trials with CAPVAXIVE® (Uncommon frequency ≥1/1,000 to < 1/100).

Blood and lymphatic system disorders: Lymphadenopathy

Gastrointestinal disorders: Diarrhea, nausea

General disorders and administration site conditions: Injection-site pruritus, chills

Nervous system disorders: Dizziness

8.3.1. Less Common Clinical Trial Adverse Reactions – Pediatrics

No other adverse reactions not listed in the other tables were reported in clinical trials with frequency of ≥1/100.

8.5. Post-Market Adverse Reactions

There are no post-marketing data available for CAPVAXIVE®.

9. Drug Interactions

9.4. Drug-Drug Interactions

Use with other vaccines
Adults 18 Years of Age and Older
CAPVAXIVE® can be administered concomitantly with inactivated influenza vaccine (see 8.2 Clinical Trial Adverse Reactions and 14 Clinical Trials). There are no data on the concomitant administration of CAPVAXIVE® with other vaccines.

Children and Adolescents 2 to Less Than 18 Years of Age
There are no data on the concomitant administration of CAPVAXIVE® with other vaccines.

10. Clinical Pharmacology

Therapeutic Class
CAPVAXIVE® is a conjugated polysaccharide vaccine that protects against invasive disease caused by *S. pneumoniae*.

10.1. Mechanism of Action

Immune responses following pneumococcal vaccination can be determined through the assessments of OPA responses to assess functional antibodies capable of opsonizing pneumococcal capsular polysaccharides for presentation to phagocytic cells for engulfment and subsequent killing. OPA responses are considered an important immunologic surrogate measure of protection against pneumococcal disease in adults. Specific threshold values that correlate with protection in adults have not been defined. There is a positive correlation between OPA responses and anti-capsular IgG responses.

Serotype specific immune responses (OPA and IgG) for the 21 serotypes contained in CAPVAXIVE® and 2 cross-reactive serotypes (15B and 6C) were measured using a validated multiplexed opsonophagocytic assay (MOPA) and pneumococcal electrochemiluminescence (Pn ECL) assay. Serotype 15C represents the immune response to the deOAc15B polysaccharide as the molecular structure for deOAc15B and 15C are similar.

As with any vaccine, CAPVAXIVE® may not protect all vaccine recipients.

11. Storage, Stability, and Disposal

Store refrigerated at 2°C to 8°C.

Do not freeze. Protect from light.

CAPVAXIVE® should be administered as soon as possible after being removed from the refrigerator.

In the event of temporary temperature excursions, stability data indicate that CAPVAXIVE® is stable at temperatures up to 25°C for 96 hours.

12. Special Handling Instructions

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

Part 2: Scientific Information

13. Pharmaceutical Information

Drug Substance
CAPVAXIVE® (Pneumococcal 21-valent Conjugate Vaccine)

Physicochemical properties: The vaccine is a colorless, clear to opalescent solution.

Product Characteristics:
CAPVAXIVE® (Pneumococcal 21-valent Conjugate Vaccine) is a sterile solution of purified capsular polysaccharides from *S. pneumoniae* serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, deOAc15B (de-O-acetylated serotype 15B), 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B individually conjugated to CRM197 carrier protein. CRM197 is a nontoxic mutant of diphtheria toxin (originating from *Corynebacterium diphtheriae* C7) expressed recombinantly in *Pseudomonas fluorescens*.

Each of the 21 serotypes is manufactured independently using a common manufacturing platform with slight variations to accommodate for differences in strains, polysaccharides, and process stream properties. The process comprises fermentation and inactivation steps to produce the inactivated pneumococcal bacteria, followed by purification steps to produce the purified polysaccharide powder. The purified polysaccharides are size reduced to a target molecular mass, chemically activated via sodium metaperiodate oxidation, and buffer exchanged by ultrafiltration. Each serotype of activated polysaccharide is then individually conjugated to CRM197 carrier protein via reductive amination. The final vaccine is prepared by blending the 21 conjugates in a final buffer containing histidine, polysorbate 20, and sodium chloride.

14. Clinical Trials

14.1. Clinical Trials by Indication

Adults 18 years of Age and Older

Table 8: Summary of Patient Demographics for Clinical Trials for Pneumococcal Disease Immunogenicity and Safety

Study #	Study design	Dosage, route of administration and duration	Vaccinated Study subjects (n)	Mean age (Range)	Sex
V116-003 [NCT05425732]	Randomized, active comparator-controlled, parallel-group, multisite, double-blind study to evaluate the safety, tolerability, and immunogenicity of CAPVAXIVE® in pneumococcal vaccine-naïve adults ≥18 years of age.	1 dose of 0.5mL of CAPVAXIVE® or PCV20 Intramuscular injection	N=2656	60.7 years (18 to 97 years)	Females: 1558 Males: 1098

Study #	Study design	Dosage, route of administration and duration	Vaccinated Study subjects (n)	Mean age (Range)	Sex
V116-004 [NCT05464420]	Randomized, active comparator-controlled, parallel-group, multisite, double-blind, lot-to-lot consistency study to evaluate the safety, tolerability, and immunogenicity of CAPVAXIVE® in pneumococcal vaccine-naïve adults 18 to 49 years of age.	1 dose of 0.5mL of CAPVAXIVE® or PPSV23 Intramuscular injection	N=2157	34.6 years (18 to 49 years)	Female: 1243 Male: 914
V116-005 [NCT05526716]	Randomized, placebo-controlled, parallel-group, multisite, double-blind study of CAPVAXIVE® to evaluate the safety, tolerability, and immunogenicity of CAPVAXIVE® when administered concomitantly with quadrivalent influenza vaccine (QIV) in adults ≥50 years of age	1 dose of 0.5mL of CAPVAXIVE® + 1 dose of 0.5mL of QIV + 1 dose of 0.5mL of placebo (concomitant administration) OR 1 dose of 0.5mL of QIV + 1 dose of 0.5mL of placebo + 1 dose of 0.5ml of CAPVAXIVE® (sequential administration) Intramuscular injection	N=1072	64.2 years (50 to 91 years)	Female: 584 Male: 488

Study #	Study design	Dosage, route of administration and duration	Vaccinated Study subjects (n)	Mean age (Range)	Sex
V116-006 [NCT05420961]	To evaluate the safety, tolerability and immunogenicity of CAPVAXIVE® in participants ≥50 years of age who were pneumococcal vaccine-experienced (PPSV23, PCV13, PCV13+ PPSV23, PCV15+PPSV23, PCV15, PCV20 or PPSV23+PCV13) Cohorts 1 and 2: Randomized, double-blind, parallel group, active comparator-controlled Cohort 3: Open-label, single group	Cohort 1: 1 dose of 0.5mL of CAPVAXIVE® or PSV15 Cohort 2: 1 dose of 0.5mL of CAPVAXIVE® or PPSV23 Cohort 3: 1 dose of 0.5mL of CAPVAXIVE® Intramuscular injection	N=712	67.9 years (50 to 91 years)	Female: 381 Male: 331
V116-007 [NCT05393037]	Double-blind, randomized, active comparator study to evaluate the safety, tolerability, and immunogenicity of V116 in adults living with HIV.	Group 1: 1 dose of 0.5mL of CAPVAXIVE® followed by 1 dose of 0.5mL placebo 8 weeks later Group 2: 1 dose of of 0.5mL of PCV15 followed by 1 dose of 0.5mL PPSV23 8 weeks later Intramuscular injection	N=312	45.3 years (19 to 86 years)	Female: 91 Male: 221

Study #	Study design	Dosage, route of administration and duration	Vaccinated Study subjects (n)	Mean age (Range)	Sex
V116-008 [NCT05696080]	Double-blind, randomized, active comparator study to evaluate the safety, tolerability, and immunogenicity of V116 in pneumococcal vaccine-naïve adults with increased risk of pneumococcal disease.	Group 1: 1 dose of 0.5mL of CAPVAXIVE® followed by 0.5mL of placebo 8 weeks later Group 2: 1 dose of 0.5mL of PCV15 followed by 0.5mL of PPSV23 8 weeks later Intramuscular injection	N=516	52.6 years (18 to 64 years)	Female: 233 Male: 283

Immunogenicity

Clinical Trials Experience in Adults 18 Years of Age and Older
Four Phase 3, clinical studies (V116-003, V116-004, V116-005, and V116-006) conducted across the Americas, Europe, and Asia Pacific evaluated the immunogenicity of CAPVAXIVE® in approximately 6,500 adults 18 years of age and older, approximately 4,500 of whom received CAPVAXIVE®. Of these adults enrolled, approximately 1,000 had received other prior pneumococcal vaccines. Approximately 34% of enrolled adults had chronic medical conditions (e.g., diabetes, renal disorders, chronic heart disease, chronic liver disease, chronic lung disease including asthma, smoking, alcoholism) known to increase the risk of invasive pneumococcal disease.

In each study, immunogenicity was assessed by serotype-specific opsonophagocytic activity (OPA) and immunoglobulin G (IgG) responses at 1-month postvaccination.

Clinical Trials Conducted in Pneumococcal Vaccine-Naïve Adults
CAPVAXIVE® effectiveness in adults against invasive pneumococcal disease was demonstrated based on comparative immunogenicity to a licensed pneumococcal vaccine (Prevnar*20).

In a double-blind study (V116-003), 2,362 pneumococcal vaccine-naïve adults 50 years of age and older were randomized to receive one single dose of either CAPVAXIVE® or Prevnar*20. The study demonstrated that CAPVAXIVE® was noninferior to Prevnar*20 for the 10 common serotypes as assessed by the GMT ratio (CAPVAXIVE®/Prevnar*20) where the noninferiority statistical criteria were met if the lower bound of the 2-sided 95% Confidence Interval (CI) was greater than 0.5. CAPVAXIVE® was superior to Prevnar*20 for 10 of 11 serotypes unique to CAPVAXIVE® as assessed by the GMT ratio (CAPVAXIVE®/Prevnar*20) where the superiority statistical criterion was met if the lower bound of the 2-sided 95% CI was greater than 2.0 (**Table 9**). The lower bound of the 2-sided 95% CI for serotype 15C was 1.77.

CAPVAXIVE® was superior to Prevnar*20 for 10 of 11 unique serotypes in CAPVAXIVE® as assessed by the proportion of individuals who achieved a ≥4-fold rise from prevaccination to 1-month postvaccination for OPA responses. The statistical criterion was defined as the lower bound of the 2-sided 95% CI of the difference between CAPVAXIVE® and Prevnar*20 being greater than 10%. For serotype 15C, 83.4% of individuals achieved a ≥4-fold rise in OPA responses from prevaccination to 1-month postvaccination; the lower bound of the 2-sided 95% CI of the difference (CAPVAXIVE® – Prevnar*20) was 5.6% and did not meet the statistical criterion for superiority of >10%. The immune response to serotype 15C in the comparator group was likely attributed to cross-reactivity based on the presence of the 15B antigen.

Table 9: Serotype Specific OPA GMTs in Pneumococcal Vaccine Naïve Adults ≥50 Years of Age (V116-003)

Pneumococcal Serotype	CAPVAXIVE® (N = 1179)		Prevnar*20 (N = 1177)		GMT Ratio[a] (CAPVAXIVE®/Prevnar*20) (95% CI)[a]
	n	GMT[a]	n	GMT[a]	
10 Common Serotypes[†]					
3	1154	274.0	1161	176.7	1.55 (1.40, 1.72)
6A	1148	2302.0	1153	2972.5	0.77 (0.68, 0.88)
7F	1152	3637.4	1158	3429.9	1.06 (0.95, 1.18)
8	1155	2501.3	1158	1811.1	1.38 (1.25, 1.53)
10A	1161	3893.4	1159	4678.0	0.83 (0.75, 0.93)
11A	1145	3232.6	1150	2092.8	1.54 (1.39, 1.72)
12F	1160	2641.2	1161	2499.6	1.06 (0.92, 1.21)
19A	1159	2136.1	1162	2817.8	0.76 (0.69, 0.84)
22F	1147	3874.5	1154	4770.1	0.81 (0.72, 0.92)
33F	1154	13558.9	1157	11742.1	1.15 (1.01, 1.32)
11 Serotypes Unique to CAPVAXIVE® [‡]					
9N	1147	7470.7	1150	1640.4	4.55 (4.12, 5.04)
15A	1107	5237.2	1102	1589.0	3.30 (2.91, 3.74)
15C	1153	4216.2	1158	2072.3	2.03 (1.77, 2.34)
16F	1151	4868.2	1153	846.3	5.75 (5.16, 6.41)
17F	1148	7764.9	1156	460.4	16.86 (14.90, 19.09)
20A	1161	6099.2	1155	631.1	9.66 (8.66, 10.79)
23A	1132	3737.2	1104	461.5	8.10 (6.86, 9.55)
23B	1160	1082.5	1160	107.3	10.09 (8.48, 12.00)
24F	1153	2728.6	1130	70.5	38.71 (33.87, 44.25)
31	1153	3132.5	1154	144.4	21.69 (18.68, 25.18)
35B	1153	8527.8	1159	1383.0	6.17 (5.59, 6.80)

[a]GMTs, GMT ratio, and 95% CI were estimated from a constrained Longitudinal Data Analysis model.
[†] A conclusion of non-inferiority for the common serotypes was based on the lower bound of the 2-sided 95% CI for the estimated GMT ratio (CAPVAXIVE®/Prevnar*20) being >0.5.
[‡] A conclusion of superiority for the unique serotypes in CAPVAXIVE® compared to Prevnar*20 was based on the lower bound of the 2-sided 95% CI for the estimated GMT ratio (CAPVAXIVE®/Prevnar*20) being >2.0.
N=Number of individuals randomized and vaccinated; n=Number of individuals contributing to the analysis.

Immunobridging in Pneumococcal Vaccine Naïve Adults 18 to 49 Years of Age

In a double-blind study (V116-003), pneumococcal vaccine-naïve individuals 18 to 49 years of age were randomized in a 2:1 ratio to receive CAPVAXIVE® or Prevnar*20.

CAPVAXIVE® successfully immunobridged serotype-specific immune responses to each of the 21 vaccine serotypes in individuals 18 to 49 years of age to individuals 50 to 64 years of age, as the lower bound of the 2-sided 95% CI for the GMT ratio for each serotype was >0.5 **Table 10**).

Table 10: Comparison of Serotype-Specific OPA GMTs in Pneumococcal Vaccine-Naïve Adults 18-49 Years of Age to 50-64 Years of Age Who Received CAPVAXIVE® (V116-003)

Pneumococcal Serotype	18-49 years N = 200		50-64 years N = 589		GMT Ratio[a],[†] (18-49 years / 50-64 years) (95% CI)*
	n	GMT*	n	GMT*	
3	194	308.6	572	282.7	1.09 (0.90, 1.33)
6A	196	5289.6	569	2572.9	2.06 (1.61, 2.62)
7F	198	6447.2	571	4278.8	1.51 (1.23, 1.84)
8	197	4516.0	571	3004.7	1.50 (1.26, 1.79)
9N	197	17283.2	570	8791.4	1.97 (1.59, 2.43)
10A	197	6808.1	575	4382.6	1.55 (1.26, 1.92)
11A	196	5871.6	564	3785.8	1.55 (1.26, 1.91)
12F	196	6150.4	574	3561.2	1.73 (1.37, 2.17)
15A	184	11319.2	550	5901.2	1.92 (1.55, 2.37)
15C	195	10194.0	570	5708.0	1.79 (1.36, 2.35)
16F	193	8877.0	571	5720.0	1.55 (1.26, 1.91)
17F	194	16070.6	568	10068.0	1.60 (1.26, 2.02)
19A	198	2773.2	574	2374.6	1.17 (0.97, 1.40)
20A	197	13150.0	575	7562.7	1.74 (1.39, 2.18)
22F	198	9299.6	568	4683.6	1.99 (1.58, 2.49)
23A	192	8848.7	561	4739.5	1.87 (1.43, 2.44)
23B	198	2140.1	575	1420.9	1.51 (1.11, 2.04)
24F	197	4137.6	570	3047.2	1.36 (1.10, 1.67)
31	195	8005.6	570	3820.7	2.10 (1.63, 2.69)
33F	197	34805.5	570	17607.4	1.98 (1.52, 2.57)
35B	198	13933.4	573	9053.9	1.54 (1.26, 1.87)

[a] GMTs, GMT ratio, and 95% CI were estimated from a Longitudinal Data Analysis model.
[†] A conclusion of immunobridging was based on the lower bound of the 2-sided 95% CI for the estimated GMT ratio (18-49 years / 50-64 years) being >0.5.
N=Number of individuals randomized and vaccinated; n=Number of individuals contributing to the analysis

Cross-reactive immune responses to CAPVAXIVE®

CAPVAXIVE® elicited an immune response to serotype 15B (cross reactive to serotype 15C) and serotype 6C (cross reactive to serotype 6A). In study 003, in individuals 50 years of age and older, CAPVAXIVE® met the predefined criterion (lower bound of the 2-sided 95% CI of the proportion of

individuals with a ≥4-fold rise in OPA responses is >50%) for antibody response to serotype 15B, with lower bound of the 2-sided 95% CI being 61.4%; the antibody response did not meet the criterion for serotype 6C, with the lower bound of the 2-sided 95% CI being 46% vs. 50%. CAPVAXIVE® successfully immunobridged serotype-specific immune response for serotype 15B in individuals 18 to 49 years of age to individuals 50 to 64 years of age, as the lower bound of the 2-sided 95% CI for the GMT ratio was >0.5. For the immune response to serotype 6C in individuals 18 to 49 years of age, as compared to individuals 50 to 64 years of age, the GMT ratio observed was 2.05 (95% CI: 1.52, 2.77).

In a double-blind study (V116-004), 2,162 pneumococcal vaccine naïve adults 18 to 49 years of age were randomized in a 1:1:1:1 ratio to receive 1 of 3 lots of CAPVAXIVE® or PNEUMOVAX® 23. The study demonstrated that all 3 lots were equivalent as the lower and upper limits of the 2sided 95% CI of the serotype specific OPA GMT ratios between any 2 lots were within the equivalence margin (0.5 to 2.0) for all 21 serotypes. Immune responses following vaccination with CAPVAXIVE® were comparable to PNEUMOVAX® 23 for the 12 common serotypes and higher for 9 unique serotypes.

Clinical Trials Conducted in Adults with Prior Pneumococcal Vaccination

V116-006, a descriptive Phase 3 study, enrolled adults ≥50 years of age who were previously vaccinated with other pneumococcal vaccines at least 1 year prior to study entry.

Adults who previously received PNEUMOVAX® 23 (double-blind cohort) were randomized to receive a single dose of either CAPVAXIVE® or VAXNEUVANCE®. CAPVAXIVE® elicited comparable immune responses as compared with VAXNEUVANCE® for the 6 common serotypes, and higher immune responses for the 15 unique serotypes.

Adults who previously received Prevnar*13 (double-blind cohort) were randomized to receive either CAPVAXIVE® or PNEUMOVAX® 23. CAPVAXIVE® elicited comparable immune responses as compared with PNEUMOVAX® 23 for the 12 common serotypes, and higher immune responses for the 9 unique serotypes.

Adults who received other prior pneumococcal vaccines (Prevnar*13 + PNEUMOVAX® 23, VAXNEUVANCE® + PNEUMOVAX® 23, PNEUMOVAX® 23 + Prevnar*13, or VAXNEUVANCE®) were allocated to receive CAPVAXIVE® (open-label cohort). CAPVAXIVE® was demonstrated to be immunogenic for all serotypes included in the vaccine, based on OPA GMTs and the proportion of individuals with ≥4-fold rise in OPA responses from baseline to 1-month postvaccination. The immune responses to CAPVAXIVE® were consistent in adults who have been vaccinated with other pneumococcal vaccines at least 1 year prior.

Concomitant Vaccination

In a double-blind study (V116-005), 1,080 adults 50 years of age and older, with or without a history of prior pneumococcal vaccination, were randomized in a 1:1 ratio. One vaccination group received CAPVAXIVE® and QIV concomitantly, followed by placebo 30 days later (concomitant group). A second vaccination group received QIV and placebo concomitantly, followed by CAPVAXIVE® 30 days later (sequential group).

CAPVAXIVE® administered concomitantly with QIV was non-inferior to CAPVAXIVE® administered sequentially after QIV for 20 of 21 serotypes contained in the vaccine as the lower bound of the 2-sided 95% CI of the GMT ratio (concomitant group/sequential group) was >0.5; the lower bound for serotype

23B was 0.44. QIV administered concomitantly with CAPVAXIVE® was non-inferior to QIV administered with placebo as assessed by influenza strain specific- hemagglutination inhibition (HAI) GMTs at 1-month postvaccination for 3 of 4 influenza strains. The lower bound of the 2-sided 95% Cis for HAI GMT ratios (concomitant group/sequential group) was >0.67 (the non-inferiority margin) for 3 of 4 influenza strains in QIV; the lower bound was 0.67 for the A/H3N2 influenza strain.

Clinical immunogenicity in Special Populations

Adults ≥18 Years of Age Individuals Living with HIV

In a double-blind study, V116-007, 313 adults living with well-managed HIV infection, with CD4+ T-cells/µL ≥50 and plasma HIV ribonucleic acid (RNA) <50,000 copies/mL, with or without a history of prior pneumococcal vaccination (i.e., ~36% vs ~64%), were randomized in a 1:1 ratio to receive either a sequential regimen of CAPVAXIVE® (PCV21) followed by placebo eight weeks later (CAPVAXIVE® + placebo), or VAXNEUVANCE® (PCV15) followed by PNEUMOVAX® 23 (PPSV23) eight weeks later (VAXNEUVANCE® + PNEUMOVAX® 23).

At screening, among all participants vaccinated, 6.7% had a CD4+ T-cell counts ≥50 to <350 cells/µL, 18.6% had CD4+ T-cell counts ≥350 to <500 cells/µL, and 74.7% had CD4+ T-cell counts ≥500 cells/µL. A majority of study participants were treated with ≥3 drug antiretroviral therapy**.**

CAPVAXIVE® was immunogenic for all 21 serotypes contained in the vaccine, as assessed by serotype specific OPA GMTs at 1-month postvaccination with CAPVAXIVE®, which elicited immune responses that were generally comparable to VAXNEUVANCE® and PNEUMOVAX® 23 for the 13 common serotypes, and higher for the 8 serotypes unique to CAPVAXIVE® as assessed by OPA GMTs at 1-month postvaccination with CAPVAXIVE® and 1-month postvaccination following VAXNEUVANCE® and 1-month postvaccination following PNEUMOVAX® 23.

Adults 18 to 64 Years of Age with Chronic Medical Conditions

In a double-blind study, V116-008, 518 pneumococcal vaccine naïve adults with one or more prespecified chronic medical conditions known to increase the risk of invasive pneumococcal disease (e.g., diabetes mellitus, chronic lung disease, chronic heart disease) were randomized in a 3:1 ratio to receive either CAPVAXIVE® followed by placebo eight weeks later (CAPVAXIVE® + placebo), or VAXNEUVANCE® followed by PNEUMOVAX® 23 eight weeks later (VAXNEUVANCE® + PNEUMOVAX® 23).

Among all vaccinated participants, 194 (37.6%) had diabetes mellitus only, 84 (16.3%) had chronic heart disease only, 23 (4.5%) had chronic kidney disease only, 34 (6.6%) had chronic liver disease only, 99 (19.2%) had chronic lung disease only, and 82 (15.9%) had ≥2 increased risk conditions.

CAPVAXIVE® was immunogenic for all 21 serotypes contained in the vaccine, as assessed by serotype-specific OPA GMTs at 1-month postvaccination with CAPVAXIVE® which elicited immune responses that were generally comparable to VAXNEUVANCE® and/or PNEUMOVAX® 23 for the 13 common serotypes, and higher for the 8 serotypes unique to CAPVAXIVE® as assessed by OPA GMTs at 1-month postvaccination with CAPVAXIVE® and 1-month postvaccination following VAXNEUVANCE® and 1-month postvaccination following PNEUMOVAX® 23.

Children and Adolescents 2 to Less Than 18 Years of Age at Increased Risk for Pneumococcal Disease due to Certain Medical Conditions

Table 11: Summary of Pediatric Patient Demographics for Clinical Trials for Pneumococcal Disease Immunogenicity and Safety

Study #	Study design	Dosage, route of administration and duration	Vaccinated Study subjects (n)	Mean age (Range)	Sex
V116-013 [NCT06177912]	Randomized, double-blind, active comparator controlled, parallel-group, multicenter study to evaluate safety, tolerability, and immunogenicity of V116 in children and adolescents aged ≥2 to <18 years with increased risk of pneumococcal disease.	1 dose of 0.5mL of CAPVAXIVE® or PPSV23 Intramuscular injection	N= 874	8.0 years (2 to 18 years)	Females: 359 Males: 515

Immunogenicity

Clinical Trials Experience in individuals 2 to less than 18 years of age at increased risk for Pneumococcal Disease and who have previously completed a primary pneumococcal vaccination regimen.

The purpose of Protocol 013 was to evaluate the safety, tolerability, and immunogenicity of V116 compared to PPSV23 in children and teenagers 2 through 17 years of age at increased risk for Pneumococcal Disease, who had completed routine pneumococcal vaccine as infants/toddlers.

In a double-blind study (V116-013), 882 individuals 2 to less than 18 years of age with one or more prespecified chronic medical conditions known to increase the risk of pneumococcal disease and who completed a primary pneumococcal vaccination regimen at least 8 weeks prior to enrollment were randomized in a 3:2 ratio to receive either CAPVAXIVE® or PNEUMOVAX® 23. Among the vaccinated participants (874), 135 (15.4%) had diabetes mellitus, 143 (16.4%) had chronic heart disease, 76 (8.7%) had chronic kidney disease, 60 (6.9%) had chronic liver disease, 499 (57.1%) had chronic lung disease, and 36 (4.1%) had ≥2 increased-risk conditions. Immunogenicity was assessed by OPA GMTs at 1-month postvaccination with either CAPVAXIVE® or PNEUMOVAX® 23.

The study demonstrated that CAPVAXIVE® was non-inferior to PNEUMOVAX® 23 for the 12 common serotypes as assessed by the GMT ratio (CAPVAXIVE®/PNEUMOVAX® 23) where the non-inferiority statistical criteria were met if the lower bounds of the 2-sided 95% CI were >0.5. CAPVAXIVE® was superior to PNEUMOVAX® 23 for the 9 serotypes unique to CAPVAXIVE® as assessed by the GMT ratio (CAPVAXIVE®/PNEUMOVAX® 23) where the superiority statistical criteria were met if the lower bounds of the 2-sided 95% CI were >2.0 (**Table 12**).

CAPVAXIVE® also elicited immune responses to serotype 15B (cross-reactive to serotype 15C). In a post hoc analysis utilizing the same prespecified non-inferiority criterion that was used for the common serotypes, CAPVAXIVE® was non-inferior to PNEUMOVAX® 23 for serotype 15B.

Table 12: Serotype-Specific OPA GMTs in Children and Adolescents 2 to Less Than 18 Years of Age with Increased Risk of Pneumococcal Disease and who have previously completed a primary pneumococcal vaccination regimen (V116-013) .

Pneumococcal Serotype	CAPVAXIVE® (N=527)		PNEUMOVAX® 23 (N=347)		GMT Ratio[a] (CAPVAXIVE®/PNEUMOVAX® 23) (95% CI)*
	n	GMT*	n	GMT*	
12 Common Serotypes[†]					
3	488	526.6	314	517.0	1.02 (0.89, 1.17)
7F	486	20618.1	315	14207.2	1.45 (1.24, 1.70)
8	485	12294.5	313	8966.9	1.37 (1.20, 1.56)
9N	485	35556.8	315	18587.8	1.91 (1.64, 2.23)
10A	485	13719.7	311	5363.8	2.56 (2.18, 3.00)
11A	486	10396.3	312	3129.8	3.32 (2.80, 3.95)
12F	486	14752.0	314	4820.1	3.06 (2.62, 3.58)
17F	481	40011.8	312	11267.4	3.55 (3.02, 4.17)
19A	486	9009.8	314	9797.6	0.92 (0.78, 1.08)
20A	480	37532.2	311	14787.0	2.54 (2.13, 3.02)
22F	487	20162.7	313	7770.3	2.59 (2.21, 3.04)
33F	488	73201.8	314	40609.0	1.80 (1.54, 2.11)
9 Serotypes Unique to CAPVAXIVE[‡]					
6A	480	16910.9	311	5653.8	2.99 (2.46, 3.64)
15A	485	69527.8	315	5332.2	13.04 (11.13, 15.27)
15C	480	34539.1	308	4398.4	7.85 (6.29, 9.81)
16F	485	31544.9	313	5449.7	5.79 (5.01, 6.69)
23A	474	28591.7	296	4882.0	5.86 (4.88, 7.03)
23B	485	5988.2	312	370.5	16.16 (12.03, 21.72)
24F	478	11102.2	297	2771.8	4.01 (3.40, 4.72)
31	484	46163.7	311	2563.0	18.01 (15.09, 21.50)
35B	482	40102.8	311	7812.5	5.13 (4.45, 5.93)

[a] GMTs, GMT ratio, and 95% CI were estimated from a constrained Longitudinal Data Analysis model.
[†] A conclusion of non-inferiority for the common serotypes was based on the lower bound of the 2-sided 95% CI for the estimated GMT ratio (CAPVAXIVE/PNEUMOVAX 23) being >0.5.
[‡] A conclusion of superiority for the unique serotypes in CAPVAXIVE compared to PNEUMOVAX 23 was based on the lower bound of the 2-sided 95% CI for the estimated GMT ratio (CAPVAXIVE/PNEUMOVAX 23) being >2.0.
N=Number of individuals randomized and vaccinated; n=Number of individuals contributing to the analysis.

15. Microbiology

No microbiological information is required for this vaccine.

16. Non-Clinical Toxicology

General Toxicology: No hazards to humans were revealed in a repeat dose toxicity study in which rats were administered 42 mcg per dose (one-half the full human dose) via intramuscular injection for 2 doses 3 weeks apart. The study also included an evaluation of single dose toxicity and local tolerance.

CAPVAXIVE® has not been evaluated for the potential to cause carcinogenicity or genotoxicity.

Reproductive and Developmental Toxicology:

CAPVAXIVE® was administered to female rats at 42 mcg per dose (one-half the full human dose) via intramuscular injection. There were no effects on mating performance, fertility, or embryonic/fetal survival and no fetal malformations or adverse effects on pre weaning development were observed.

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

CAPVAXIVE®

Pneumococcal 21-valent Conjugate Vaccine

This patient medication information is written for the person who will be taking **CAPVAXIVE®**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This patient medication information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **CAPVAXIVE®**, talk to a healthcare professional.

What CAPVAXIVE® is used for:

- **CAPVAXIVE®** is a vaccine for adults 18 years of age and older, as well as for children and adolescents 2 to less than 18 years of age who are at increased risk for pneumococcal disease and who have previously completed a primary pneumococcal vaccination regimen. CAPVAXIVE® helps protect against invasive (severe) pneumococcal disease caused by bacteria called pneumococcus. These bacteria can cause many types of illnesses, which can be invasive (severe), such as infections in:
    - your lungs (called bacteremic pneumonia)
    - the area around the brain and spinal cord (called meningitis).
    - your blood (called bacteremia).

These illnesses are more likely to happen in people who are older or have health conditions (such as alcoholism, asthma, diabetes; heart problems, HIV (human immunodeficiency virus) infection, liver problems, lung problems, kidney problems, or smoking).

How CAPVAXIVE® works:

The vaccine works by helping the body to make its own antibodies which can protect you or your child against invasive pneumococcal disease caused by the types of pneumococcus covered by the vaccine.

The ingredients in CAPVAXIVE® are:

Medicinal ingredients: bacterial sugars from 21 types of pneumococcus each linked to a protein (CRM197) as the active ingredient. The sugars from these bacteria and the protein are not alive and do not cause disease.

Non-medicinal ingredients: L-histidine, polysorbate 20, sodium chloride, water. CAPVAXIVE® does not have any preservatives.

CAPVAXIVE® comes in the following dosage forms:

- 0.5 mL prefilled syringes

Do not use CAPVAXIVE® if:

- You or your child are allergic to any of the ingredients in CAPVAXIVE® including diphtheria toxoid.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you or your child are given CAPVAXIVE®. Talk about any health conditions or problems you or your child may have, or have had including:

- any allergies
- a weak immune system (which means your body is less able to fight off infections)
- medicines or treatments that might make your immune system weak
- have any bleeding problems or bruise easily.

Tell your healthcare professional if you or your child:

- are pregnant or planning to become pregnant. They will tell you if you should receive CAPVAXIVE®.
- are breast-feeding or intend to breast-feed. Your healthcare professional will tell you if you should receive CAPVAXIVE®.

Other warnings you should know about:
As with other vaccines, CAPVAXIVE® may not fully protect all those who get the vaccine.
CAPVAXIVE® has not been studied in children who are under 2 years of age.

Use of CAPVAXIVE® with other vaccines and medicines

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

CAPVAXIVE® can be given to adults at the same time as flu (inactivated influenza) vaccine.

How is CAPVAXIVE® given:

- CAPVAXIVE® is given as an injection into the muscle.

Usual dose:
Adults and children need one dose of the vaccine.

Overdose:
Overdose with CAPVAXIVE® 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 CAPVAXIVE®, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed Dose:
CAPVAXIVE® is a single dose vaccine.

Possible side effects from using CAPVAXIVE®?
As with any vaccine, this vaccine can cause side effects, although not everybody gets them.

These are not all the possible side effects you may have when given CAPVAXIVE®. If you experience any side effects not listed here, tell your healthcare professional.

The following side effects seen with CAPVAXIVE® in individuals 2 years of age an older include:

Common: may occur in more than 1 in 10 individuals

- Pain, redness, or swelling where you got the shot
- Feeling tired
- Headache
- Muscle aches

Less common: may occur in more than 1 in 100 and up to 1 in 10 individuals

- Fever

Uncommon: may occur in more than 1 in 1000 and up to 1 in 100 individuals

- Diarrhea, nausea
- Itching at the injection site
- Swollen glands in the neck, armpit, or groin
- Chills
- Dizziness

Additional side effects of CAPVAXIVE® in children and adolescents are:

Common: may occur in more than 1 in 10 individuals

- Feeling of illness, discomfort, or unease
- Being more fussy than usual

Less common: may occur in more than 1 in 100 and up to 1 in 10 individuals

- Being more sleepy than usual
- Joint pain

These side effects are generally mild and last a short time.

Tell your healthcare provider about these side effects or any unusual symptoms that develop after you or your child get this vaccine. Get medical care right away if you or your child have symptoms of an allergic reaction, which may include:

- Wheezing or trouble breathing
- Swelling of the face, lips, or tongue
- Hives
- Rash

These are not all the possible side effects you or your child may have when getting CAPVAXIVE®. There may be side effects not listed here. Ask your healthcare professional for more information.

If you or your child have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting suspected side effects for vaccines

For the general public: Should you or your child 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 (PHAC), Health Canada (HC) and Merck Canada Inc. 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 (https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization/form.html) and send it to your local Health Unit.

Storage:

Store refrigerated at 2°C to 8°C. Do not freeze. Protect from light.

Keep out of reach and sight of children.

If you want more information about CAPVAXIVE®:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website www.merck.ca; or by calling 1-800-567-2594.

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