

## PART III: CONSUMER INFORMATION

### Pprevnar® 13

#### Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM<sub>197</sub> Protein)

This leaflet is part III of a three-part "Product Monograph" published when Pprevnar® 13 was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Pprevnar® 13. Contact your doctor, nurse or pharmacist if you have any questions about the vaccine.

#### ABOUT THIS VACCINE

##### What the vaccine is used for:

Pprevnar 13 is a pneumococcal vaccine given to:

- **Children from 6 weeks to 5 years** to help protect against diseases such as: bacteraemic pneumonia (lung infection with bacteria in the blood stream), sepsis or bacteraemia (bacteria in the blood stream), meningitis (inflammation around the brain) and ear infections.
- **Children from 6 years to 17 years** to help protect against diseases such as: bacteraemic pneumonia (lung infection with bacteria in the blood stream), sepsis or bacteraemia (bacteria in the blood stream), and meningitis (inflammation around the brain).
- **Adults aged 18 years and older** to help prevent diseases such as: pneumonia (lung infection), bacteraemic pneumonia (lung infection with bacteria in the blood stream), sepsis or bacteraemia (bacteria in the blood stream), and meningitis (inflammation around the brain).

##### What it does:

The vaccine works by helping the body to make its own antibodies, which protects you or your child against diseases caused by thirteen types of the bacteria *Streptococcus pneumoniae*.

##### When it should not be used:

If you or your child is allergic (hypersensitive) to the active substances, to any other ingredients, or to any other vaccine that contains diphtheria toxoid.

##### What the medicinal ingredient is:

The active substances are:

- 2.2 µg of saccharide for serotypes 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19A, 19F and 23F
- 4.4 µg of saccharide for serotype 6B

Conjugated to CRM<sub>197</sub> carrier protein and adsorbed on aluminum phosphate (0.125 mg aluminum).

##### What the important nonmedicinal ingredients are:

Sodium chloride, succinic acid, Polysorbate 80 and water for injection.

##### What dosage forms it comes in:

The vaccine is a white suspension for injection and provided in a single-dose, pre-filled syringe (0.5 mL). Pack size of 1 or 10, without needle.

#### WARNINGS AND PRECAUTIONS

##### Serious Warnings and Precautions

Take special care with Pprevnar 13:

- If you or your child has any present or past medical problems after any dose of Pprevnar (7-valent) or Pprevnar 13
- If you or your child is sick with a high fever
- If you or your child has any bleeding problems

Pprevnar 13 will only protect against disease caused by the types of *Streptococcus pneumoniae* in the vaccine.

As with any vaccine, Pprevnar 13 will not protect 100% of those who receive the vaccine.

##### **BEFORE you use Pprevnar 13 talk to your doctor or pharmacist:**

Please tell your doctor, nurse or pharmacist if you or your child is taking, or has recently taken any other medicines, including medicines obtained without prescription, or has recently received any other vaccine.

Increased reporting rates of seizures (fits), with or without fever, and collapse or shock-like state were observed when Pprevnar 13 was given at the same time as *Infanrix hexa*.

Some of the effects mentioned under the section "Side Effects and What To Do About Them" may temporarily affect the ability to drive or use machines.

#### INTERACTIONS WITH THIS VACCINE

**The vaccine is not to be mixed with other vaccines/products in the same syringe.**

**Different injectable vaccines should always be given at different vaccination-sites.**

#### PROPER USE OF THIS VACCINE

##### Usual dose:

The doctor or nurse will inject the recommended dose (0.5 mL) of the vaccine into you or your child's arm or leg muscle.

##### Infants and children

Typically, your child should receive 3 or 4 doses of the vaccine. According to official recommendations in your province, an alternative schedule may be used by your health care provider. Each dose will be given on a separate occasion. It is important to follow the instructions from the doctor/nurse so that your child completes the course of injections.

Premature infants (born < 37 weeks of gestation) should receive the vaccine according to the same schedule as full-term infants.

Pevnar 13 can be given at the same time as other childhood vaccines; in this case, different vaccination-sites should be used. Pevnar 13 should not be mixed with any other vaccines in the same syringe.

Children and adolescents 6 to 17 years of age (prior to 18<sup>th</sup> birthday)

Pevnar 13 is to be administered as a single dose to children and adolescents 6 to 17 years of age.

Adults aged 18 years and older

Pevnar 13 is to be administered as a single dose to adults 18 years and older including those previously vaccinated with pneumococcal polysaccharide vaccine.

The need for revaccination with a subsequent dose of Pevnar 13 has not been established.

Special populations

Individuals not previously vaccinated with Pevnar 13 and considered to be at a higher risk of pneumococcal infection (such as those with sickle cell disease or HIV infection) may receive 1 dose of Pevnar 13, including those previously vaccinated with pneumococcal polysaccharide vaccine.

Individuals with a stem cell transplant (blood-forming) may receive 3 injections, with the first given at 3 to 6 months after the transplant and with an interval of at least 1 month between doses. A fourth injection (booster) is recommended 6 months after the third injection.

**Overdose:**

Overdose with Pevnar 13 is unlikely due to it being in a pre-filled syringe.

In case of overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

**Missed Dose:**

If you forget to go back to the doctor or nurse at the scheduled time, ask the doctor or nurse for advice.

If you have any further questions on the use of Pevnar 13, ask your doctor.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Like all vaccines, Pevnar 13 can cause side effects, although not everybody gets them.

The following side effects include those reported for Pevnar 13 in infants and children aged 6 weeks to 5 years.

The most common side effects reported in at least 1 in 10 children

are:

- Decreased appetite
- Irritability
- Drowsiness/increased sleep, restless sleep/decreased sleep
- Fever; any pain, tenderness, redness, swelling or hardness at the vaccination-site

Common side effects reported in at least 1 in 100 children, but less than 1 in 10 children are:

- Diarrhea, vomiting
- Rash
- Fever > 39°C, pain or tenderness at the vaccination-site interfering with movement

Uncommon side effects reported in at least 1 in 1,000 children, but less than 1 in 100 children are:

- Crying
- Seizures (including febrile seizures)
- Urticaria or urticaria-like rash
- Redness, swelling, or hardness at the vaccination-site > 7.0 cm

Rare side effects reported in at least 1 in 10,000 children, but less than 1 in 1,000 children are:

- Hypotonic-hyporesponsive episode (collapse or shock-like state)
- Hypersensitivity reaction including swelling of the face and/or lips, difficulty in breathing

In babies born very prematurely (at or before 28 weeks of gestation), longer gaps than normal between breaths may occur for 2-3 days after vaccination.

The following side effects include those reported for Pevnar 13 in children and adolescents aged 5-17 years of age.

The most common side effects reported in at least 1 in 10 children and adolescents 5-17 years of age were:

- Decreased appetite
- Irritability
- Any pain, tenderness (including impaired movement), redness, swelling or hardness at the vaccination-site
- Drowsiness/increased sleep, restless sleep/decreased sleep

Common side effects reported in at least 1 in 100 but less than 1 in 10 children and adolescents 5-17 years of age were:

- Hives (urticaria)
- Fever

Children and adolescents aged 6-17 years with sickle cell disease or with HIV infection, and children and adolescents aged 2-17 years with a blood-forming stem cell transplant, generally had similar frequencies of side effects as healthy children and adolescents aged 5-17 years; however, the frequencies of muscle pain, fatigue, headache, joint pain, vomiting, fever and diarrhea were very common (>1/10).

Other side effects observed in other age groups may also be applicable in this age group but due to the small sample size in this study were not seen.

The following side effects include those reported for Prevnar 13 in adults aged 18 years and older.

The most common side effects reported in at least 1 in 10 adults are:

- Decreased appetite
- Headache
- Diarrhea; vomiting (in adults aged 18-49 years)
- Rash
- New joint pain/aggravated joint pain; new muscle pain/aggravated muscle pain
- Chills; fatigue; any pain, tenderness, redness, swelling or hardness at the injection site; limitation of arm movement

Common side effects reported in at least 1 in 100 adults, but less than 1 in 10 adults are:

- Vomiting (in adults aged 50 years and over)
- Fever

Uncommon side effects reported in at least 1 in 1,000 adults, but less than 1 in 100 adults are:

- Nausea
- Hypersensitivity reaction including swelling of the face and/or lips, difficulty breathing
- Enlarged lymph nodes (lymphadenopathy) in the region of the injection site.

Adults 18 years and older with HIV infection, or with a blood-forming stem cell transplant, had similar frequencies of side effects as healthy adults 18 years and older, however the frequencies of fever were very common (>1/10).

Other side effects have been seen with Prevnar 13 since being introduced onto the market:

- Enlarged lymph nodes (lymphadenopathy) in the region of the vaccination-site
- Anaphylactic/anaphylactoid reaction including shock (cardiovascular collapse)
- Angioneurotic edema, erythema multiforme
- Vaccination-site dermatitis, vaccination-site urticaria, vaccination-site pruritus

Please speak with your doctor or pharmacist should you have any questions or concerns. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptom / effect		Talk with your doctor or pharmacist	
		Only if severe	In all cases
<b>Common</b>	Diarrhea; vomiting	✓	
	Rash	✓	
	Fever greater than 39°C		✓
	Vaccination-site swelling	✓	
<b>Uncommon</b>	Seizures		✓
<b>Rare</b>	Hypotonic-hyporesponsive episode (collapse or shock-like state)		✓
	Hypersensitivity reaction including facial swelling, difficulty breathing		✓

*This is not a complete list of side effects. For any unexpected effects while taking Prevnar 13, contact your doctor or pharmacist.*

**HOW TO STORE IT**

Keep out of the reach and sight of children.

Store in a refrigerator (2°C – 8°C).

Do not freeze.

Do not use Prevnar 13 after the expiry date stated on the carton and label. The expiry date refers to the last day of that month. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**REPORTING SUSPECTED SIDE EFFECTS**

To monitor vaccine safety, the Public Health Agency of Canada collects case reports on adverse events following immunization.

**For Health Care Professionals:**

If a patient experiences an adverse event following immunization, please complete the appropriate Adverse Events Following Immunization (AEFI) Form and send it to your local Health Unit in your province/territory.

**For the General Public:**

Should you experience an adverse event following immunization, please ask your doctor, nurse, or pharmacist to complete the Adverse Events Following Immunization (AEFI) Form.

If you have any questions or have difficulties contacting your local health unit, please contact Vaccine Safety Section at Public Health Agency of Canada.

By toll-free telephone: 866-844-0018

By toll-free fax: 866-844-5931

Email: [caefi@phac-aspc.gc.ca](mailto:caefi@phac-aspc.gc.ca)

Web: <http://www.phac-aspc.gc.ca/im/vs-sv/index-eng.php>

**Mail:**

The Public Health Agency of Canada  
Vaccine Safety Section  
130 Colonnade Road, A/L 6502A  
Ottawa, ON K1A 0K9

*NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying the Public Health Agency of Canada. The Public Health Agency of Canada does not provide medical advice.*

**MORE INFORMATION**

This document plus the full product monograph, prepared for health professionals can be found at [www.pfizer.ca](http://www.pfizer.ca) or can be obtained by contacting the sponsor, Pfizer Canada ULC, at: 1-800-463-6001 (Medical Information).

This leaflet was prepared by Pfizer Canada ULC

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