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 or your child receive **PREVNAR 20**. This leaflet is a summary and will not tell you everything about this vaccine. Talk to your healthcare professional about you or your child's 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:

- Children from 6 weeks through 17 years of age (prior to the 18th birthday) to prevent invasive pneumococcal diseases such as 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*.
- 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*.

These illnesses are more likely to occur in individuals with certain diseases or behaviours, such as smoking.

How does PREVNAR 20 work?

This vaccine works by helping the body to make its own antibodies, which protect 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 or your child 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 or your child receive PREVNAR 20. Talk about any health conditions or problems you or your child may have, including if you or your child:

- 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/your child may not get the full benefit from PREVNAR 20.

If you or your child 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.

Talk to your healthcare professional before the vaccination if your child is an infant and was born very prematurely (at or before 28 weeks of gestation) as longer gaps than normal between breaths may occur for 2-3 days after vaccination.

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 or your child take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

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

Your child may be given PREVNAR 20 at the same time as other routine childhood vaccines.

In adults, PREVNAR 20 can be given at the same time as the flu (inactivated influenza) vaccine or the COVID-19 mRNA vaccine.

How PREVNAR 20 is given:

A healthcare professional will inject the recommended dose (0.5 mL) of the vaccine into your upper arm, or your child's upper arm or thigh muscle.

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

Usual dose:

Infants 6 Weeks to 15 Months of Age
Infants may receive 3 doses of the vaccine through 6 months of age. The first dose may be given from the age of 6 weeks, with doses given about 2 months apart. An additional dose is given to toddlers between 11 through 15 months of age. Your healthcare professional will tell you when your child should receive their next dose.

It is important to follow the instructions from your healthcare professional so that your child completes the course of vaccinations. If not, your child may not be fully protected from the disease.

Unvaccinated Children and Adolescents 7 Months Through 17 Years of Age
Children 7 months through 17 years of age who have never received a pneumococcal conjugate vaccine may receive PREVNAR 20 according to the following schedules:

- Infants 7 months through 11 months of age: 3 doses, with the first 2 doses given at least 4 weeks apart, and the third dose given after the 1st birthday
- Children 12 through 23 months of age: 2 doses, at least 2 months apart
- Children and adolescents 2 through 17 years of age: 1 dose

Previously Vaccinated Children and Adolescents 6 Through 17 Years of Age
Children and adolescents previously vaccinated with PREVNAR 13 may receive a single dose of PREVNAR 20.

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

Special Populations
Individuals considered to be at a higher risk of pneumococcal infection (such as those with sickle cell disease or HIV infection), including those previously vaccinated with 23-valent pneumococcal polysaccharide vaccine, may receive at least 1 dose of PREVNAR 20.

Individuals with a blood-forming stem cell transplant may initially receive 3 doses, with the first dose given at 3 to 6 months after the transplant and with an interval of at least 4 weeks between doses. A fourth (booster) dose is recommended 6 months after the third dose.

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.

Missed dose:

If your child misses a dose, talk to your healthcare professional about what steps need to be taken to protect your child.

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 infants and children (6 weeks to less than 5 years of age):

Very common: may occur in more than 1 in 10 individuals
- Decreased appetite
- Irritability
- Feeling sleepy
- Fever
- At the injection site for all children: redness, swelling or hardness, pain or tenderness
- At the injection site after the booster dose and in children 2 to 5 years of age: redness, swelling or hardness greater than 2.0 to 7.0 cm

Common: may occur in more than 1 in 100 and up to 1 in 10 individuals
- Diarrhea
- Vomiting
- Rash
- Fever (38.9°C or higher)
- At the injection site after the initial course of injections: redness, hardness, swelling of greater than 2.0 to 7.0 cm

Uncommon: may occur in more than 1 in 1000 and up to 1 in 100 individuals
- Seizures (or fits), including those caused by a high temperature
- Hives (urticaria or urticaria-like rash)

- At the injection site: redness, swelling, or hardness of more than 7.0 cm; pain or tenderness interfering with movement

Rare: may occur with up to 1 in 1,000 individuals
- Injection site allergic (hypersensitivity) reaction

The following side effects include those reported for PREVNAR 20 in children and adolescents (5 through 17 years of age):

Very common: may occur in more than 1 in 10 individuals
- Headache
- Muscle pain
- At the injection site: pain, tenderness, redness, swelling or hardness.
- Tiredness

Common: may occur in more than 1 in 100 and up to 1 in 10 individuals
- Joint pain
- At the Injection site: pain or tenderness interfering with movement

Uncommon: may occur in more than 1 in 1000 and up to 1 in 100 individuals
- Hives (urticaria or urticaria-like rash)
- Fever

Children and adolescents with either HIV infection, sickle cell disease or a blood-forming stem cell transplant vaccinated with PREVNAR 13 had similar side effects, however, the frequencies of headache, vomiting, diarrhea, fever, fatigue, joint and muscle pain were very common (>1/10).

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

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 in postmarketing experience and may also be seen with PREVNAR 20:

- Severe allergic reaction, shock or cardiovascular collapse; swelling of lips, face or throat (angioedema)
- Enlarged lymph nodes or glands (lymphadenopathy) near the vaccination site, such as under the arm or in the groin
- At the injection site: hives (urticaria), redness and irritation (dermatitis) and itching (pruritus)
- A rash causing itchy red blotches (erythema multiforme)

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

Tell your healthcare professional immediately if you or your child have symptoms of an allergic reaction, such as swelling of the face, lips, mouth tongue or throat, shortness of breath, or wheezing.

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).

This leaflet was prepared by Pfizer Canada ULC.

Last Revised November 16, 2023