PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PREVNAR 20™

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

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

What is PREVNAR 20 used for?

PREVNAR 20 is a pneumococcal vaccine given to:

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

How does PREVNAR 20 work?

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

What are the ingredients in PREVNAR 20?

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

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

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

PREVNAR 20 comes in the following dosage forms:

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

Do not use PREVNAR 20 if:

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

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

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

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

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

Other warnings you should know about:

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

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

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

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

How PREVNAR 20 is given:

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

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

Usual dose:

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

Overdose:

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

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

What are possible side effects from using PREVNAR 20?

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

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

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

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

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

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

- Severe allergic reaction, shock or cardiovascular collapse

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

Reporting Suspected Side Effects for Vaccines

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

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

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

Storage:

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

Do not freeze. Discard if vaccine has been frozen.

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

Keep out of reach and sight of children.

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

Ask your pharmacist how to throw away any unused vaccine.

If you want more information about PREVNAR 20:

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

This leaflet was prepared by Pfizer Canada ULC.

Last Revised May 9, 2022