Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Prevenar® 20
Suspension for injection

Each dose (0.5 ml) contains:
2.2 micrograms of pneumococcal polysaccharide for serotypes 1, 3, 4, 5, 6A, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, 33F

4.4 micrograms of pneumococcal polysaccharide for serotype 6B
conjugated to approximately 51 micrograms CRM_{197} carrier protein, adsorbed on aluminium phosphate (0.125 mg aluminium).

Inactive ingredients and allergens: See section 2 under 'Important information about some of this medicine's ingredients' and section 6 'Further information'.

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you or your child. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Active immunisation for the prevention of pneumococcal disease caused by serotypes of *Streptococcus pneumoniae* 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, 33F, in infants, children and adolescents from 6 weeks of age to less than 18 years of age.

Active immunisation for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* in adults 18 years of age and older.

Therapeutic group: Pneumococcal vaccine.

Prevenar 20 helps to provide protection against infections caused by 20 types (serotypes) of *Streptococcus pneumoniae* bacteria.

Prevenar 20 helps the body to make its own protection (antibodies) against the bacteria. These antibodies help protect you or your child from pneumococcal disease.

2. BEFORE USING THIS MEDICINE
Do not use this medicine if:

- you or your child are sensitive (allergic) to the active ingredients or to any of the other ingredients in this medicine (see section 6), or to other vaccines containing diphtheria toxoid.

Special warnings regarding use of the medicine
Before vaccination with Prevenar 20, tell your doctor if you or your child:
- have or have had a medical problem after any dose of Prevenar 20, such as an allergic reaction or problems with breathing.
- have a severe illness or high fever. However, a mild fever or upper respiratory tract infection (for example having a cold) itself is not a reason to delay vaccination.
- have bleeding problems or bruise easily.

- have a weakened immune system (such as due to HIV infection): you may not get the full benefit from Prevenar 20.

Before vaccination, tell your doctor if your child 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.
As with any vaccine, Prevenar 20 may not protect all persons who are vaccinated.

Prevenar 20 will only protect against ear infections in children caused by the *Streptococcus pneumoniae* strains included in the vaccine. It will not protect against other infectious agents that can cause ear infections.

Other medicines or vaccines and Prevenar 20
If you or your child are taking or have recently taken, other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.

Prevenar 20 may be given at the same time as other routine childhood vaccines.

In adults, Prevenar 20 can be given at the same time as the seasonal flu (inactivated influenza) vaccine at different injection sites on the body. Depending on the individual risk assessment of your doctor, separation of both vaccinations, e.g. an interval of 4 weeks, might be advised.

In adults, Prevenar 20 can be given at the same time as the COVID-19 mRNA vaccine (an active vaccine intended to prevent the COVID-19 disease caused by the SARS-CoV-2 coronavirus).

Tell your doctor or nurse if you or your child have recently received any other vaccine.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you are pregnant or are planning to become pregnant, consult your doctor before receiving this vaccine.
There are no data on the use of Prevenar 20 in pregnant women.
Animal studies do not indicate harmful effects on pregnancy.

It is not known whether Prevenar 20 is excreted into breast milk.

Driving and using machines
Prevenar 20 has no or negligible influence on the ability to drive or operate machines. However, some of the effects mentioned in section 4 'Side effects' may temporarily affect your ability to drive or use machines.

Important information about some of this medicine’s ingredients
Prevenar 20 contains 0.1 mg of polysorbate 80 per dose. Polysorbates may cause allergic reactions. Tell your doctor if you or your child have any known allergies.

Prevenar 20 contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. HOW TO USE THIS MEDICINE?
Always use this medicine according to your doctor's instructions.
Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicine.
The dosage and treatment regimen will be determined by your doctor only.

The vaccination schedule for Prevenar 20 will be determined in accordance with the official national immunization guidelines issued by the Ministry of Health.

This vaccine is administered by a doctor or nurse by intramuscular injection, into your upper arm or your child's upper arm or thigh muscle.

The doctor or nurse will tell you when your child should come back for the next dose.

Adults should receive only 1 injection.

Tell your doctor or nurse if you have received a pneumococcal vaccine before.

Do not exceed the recommended dose.

Adhere to the treatment as recommended by your doctor.

If you or your child have received an overdose, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

Do not take medicines in the dark! Check the label and dose <u>each time</u> you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Prevenar 20 may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

<u>Serious side effects</u>

Tell your doctor immediately if you notice signs of the following serious side effect (see also section 2 'Before using this medicine'):
Swelling of the face, lips, mouth, tongue or throat (oedema), shortness of breath (dyspnoea), wheezing (bronchospasm) – these may be signs of a severe allergic reaction such as anaphylaxis, including shock.

Additional side effects:

<u>Side effects in infants and children from 6 weeks to less than 5 years of age:</u>

Very common side effects (occur in more than 1 in 10 users):

- Decreased appetite
- Irritability
- Feeling sleepy
- Fever
- At the injection site for all children: redness, hardness or swelling, pain or tenderness
- At the injection site after the booster dose and in children aged 2-5 years: redness, hardness or swelling of greater than 2.0 to 7.0 cm

Common side effects (occur in 1-10 in 100 users):

- Diarrhoea
- Vomiting
- Rash
- Fever (high temperature of 38.9°C or higher)

- At the injection site after the initial course of vaccination: redness, hardness or swelling of greater than 2.0 to 7.0 cm, pain or tenderness interfering with movement

Uncommon side effects (occur in 1-10 in 1,000 users):
- Seizures (or fits), including those caused by a high fever
- Hives (urticaria or urticaria-like rash)
- At the injection site: redness, hardness or swelling of more than 7.0 cm

Rare side effects (occur in 1-10 in 10,000 users):
- Injection site allergic (hypersensitivity) reaction

The following side effects were observed with Prevenar 13 and may also occur with Prevenar 20:
- Collapse or shock-like state
- Allergic (hypersensitivity) reaction, including swelling of the lips and/or face
- Crying
- Restless sleep

Side effects in children and adolescents aged 5 years to less than 18 years of age:

Very common side effects (occur in more than 1 in 10 users):
- Headache
- Muscle pain
- At the injection site: pain, tenderness, redness, hardness or swelling
- Tiredness

Common side effects (occur in 1-10 in 100 users):
- Joint pain
- At the injection site: pain or tenderness interfering with movement

Uncommon side effects (occur in 1-10 in 1,000 users):
- Hives (urticaria or urticaria-like rash)
- Fever

The following side effects were observed with Prevenar 13 and may also occur with Prevenar 20:
- Diarrhoea
- Vomiting
- Decreased appetite
- Irritability
- Feeling sleepy
- Restless sleep
- Rash

Children and adolescents with HIV infection, sickle cell anaemia or a blood-forming stem cell transplant had similar side effects, however, the frequencies of the following side effects were very common: vomiting, diarrhoea, fever, joint pain, pain or tenderness at the injection site that interfere with movement.

The following side effects were observed with postmarketing use of Prevenar 13 in children and may also occur with Prevenar 20:
- Severe allergic reaction including anaphylactic shock; swelling of lips, face or throat (angioedema)

- Enlarged lymph nodes near the injection 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)

Side effects in adults:

Very common side effects (occur in more than 1 in 10 users):
- Headache
- Joint pain and muscle pain
- Pain/tenderness at the injection site and tiredness

Common side effects (occur in 1-10 in 100 users):
- Swelling at the injection site, redness at the injection site and fever

Uncommon side effects (occur in 1-10 in 1,000 users):
- Diarrhoea, nausea and vomiting
- Rash and swelling of the face, lips, mouth, tongue or throat, which may cause difficulty in swallowing or breathing (angioedema)
- Itching at the injection site, swollen glands in the neck, armpit or groin (lymphadenopathy), hives at the injection site (urticaria), and chills

The following side effects were observed with Prevenar 13 and may also occur with Prevenar 20:
- A rash causing itchy red blotches (erythema multiforme)
- Irritation at the injection site
- Decreased appetite
- Limitation of arm movement

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects or by using the link: https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store in a refrigerator (2°C-8°C). Do not freeze. Discard if the vaccine has been frozen.
- Prevenar 20 should be used as soon as possible after being removed from refrigeration.
- Prevenar 20 is stable for 96 hours when stored at temperatures from 8°C to 25°C, or 72 hours when stored at temperatures from 0°C to 2°C. At the end of this period, the product should be used or discarded. This information is intended for healthcare professionals only in case of temporary temperature excursion only.
- Pre-filled syringes should be stored horizontally to minimise the resuspension time.
- Shake vigorously before injection to obtain a homogeneous suspension.

6. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains:
sodium chloride, succinic acid, polysorbate 80, water for injection.

What the medicine looks like and contents of the pack:
Prevenar 20 is supplied as a white suspension provided in a single-dose, pre-filled 0.5 ml syringe.
The pack contains 1 or 10 pre-filled syringes with or without a needle.

Not all pack sizes may be marketed.

Registration holder and address:
Pfizer Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 172-68-37443-00

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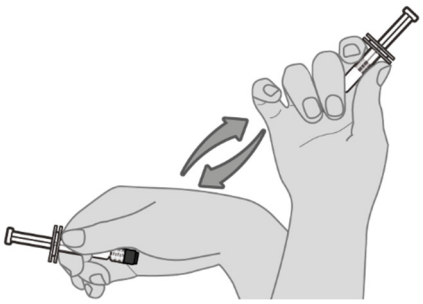
The following information is intended for healthcare professionals only:

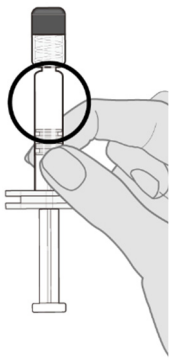
During storage, a white deposit and clear supernatant may be observed. This does not constitute a sign of deterioration. Pre-filled syringes should be stored horizontally to minimise the resuspension time.

<u>Preparation for administration</u>

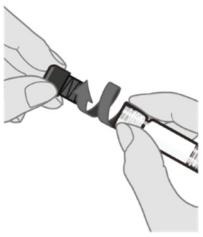
Step 1. Vaccine resuspension
Hold the pre-filled syringe horizontally between the thumb and the forefinger and shake vigorously until the contents of the syringe are a homogeneous white suspension. Do not use the vaccine if it cannot be resuspended.



Step 2. Visual inspection
Visually inspect the vaccine for large particulate matter and discolouration prior to administration. Do not use if large particulate matter or discolouration is found. If the vaccine is not a homogenous white suspension, repeat steps 1 and 2.



Step 3. Remove syringe cap
Remove the syringe cap from the Luer lock adapter by slowly turning the cap counterclockwise while holding the Luer lock adapter.



Note: Care should be taken to ensure that the extended plunger rod is not depressed while removing the syringe cap.

Step 4. Attach a sterile needle
Attach a needle appropriate for intramuscular administration to the pre-filled syringe by holding the Luer lock adapter and turning the needle clockwise.

Administer the entire dose.

Prevenar 20 is for intramuscular use only.

Prevenar 20 must not be mixed with any other vaccines or medicinal products in the same syringe.

Prevenar 20 may be given at the same time as other routine childhood vaccines; in this case, different vaccination sites on the body should be used.

Prevenar 20 may be given to adults at the same time as the seasonal influenza vaccine (QIV; surface antigen, inactivated, adjuvanted). In individuals with underlying conditions associated with a high risk of developing life-threatening pneumococcal disease, consideration may be given to separating administrations of QIV and Prevenar 20 (e.g., by approximately 4 weeks). Different vaccination sites should be used.

Prevenar 20 can be given to adults at the same time as the COVID-19 mRNA vaccine (nucleoside modified).

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