Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Prevenar 13®

Suspension for injection

Each dose (0.5 ml) contains:

pneumococcal polysaccharide serotype 1/3/4/5/6A/7F/9V/14/18C/19A/19F/23F 2.2 mcg each
pneumococcal polysaccharide serotype 6B 4.4 mcg
conjugated to approximately 32 mcg CRM_{197} carrier protein and adsorbed on aluminium (0.125 mg) phosphate

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. 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 immunization for the prevention of invasive disease, pneumonia and acute ear infection caused by *Streptococcus pneumoniae* in infants, children, and adolescents, from 6 weeks to 17 years of age.

Active immunization for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* in adults aged 18 years and above and in the elderly.

Therapeutic group: pneumococcal vaccine.
Prevenar 13® works by helping the body to make its own protection (antibodies) against the bacteria. These antibodies help protect you from a pneumococcal disease.
Prevenar 13® helps to provide protection against infections caused by 13 types (serotypes) of *Streptococcus pneumoniae* bacteria.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- You or your child is sensitive (allergic) to the active ingredients or to any of the other ingredients in this medicine (see section 6) or to the diphtheria toxoid.
- You or your child has a severe infection with high fever (over 38°C). If this happens, the vaccination should be postponed until you or your child is feeling better. However, talk to your doctor or nurse before you receive Prevenar 13® if you are not sure.

Special warnings regarding use of the medicine
Before vaccination with Prevenar 13®, tell your doctor if you or your child:

- has any present or past medical problem after receiving a dose of Prevenar® or Prevenar 13® such as an allergic reaction or problems with breathing
- has any bleeding problems or bruises easily
- has a weakened immune system (such as due to HIV infection), which could prevent you or your child from getting the full benefit from the vaccine
- has experienced seizures; you should take medicines to lower fever before Prevenar 13® vaccine is given. If your child becomes unresponsive or experiences seizures (fits) after the vaccination, contact your doctor immediately. See also section 4 “Side effects”.

Before vaccination, tell your doctor if your child was born prematurely (at or before 28 weeks of pregnancy), as longer gaps than normal between breaths may occur for 2-3 days after vaccination. See also section 4 “Side effects”.

If any of these conditions apply to you or your child (or you are not sure), consult your doctor or nurse before you receive Prevenar 13®.

As with any vaccine, Prevenar 13® may not protect everyone who is vaccinated.

Prevenar 13® only protects against ear infections in children that are caused by the types of *Streptococcus pneumoniae* bacteria included in the vaccine. The vaccine will not protect against ear infections caused by other types of infectious agents.

Other medicines or vaccines and Prevenar 13®
If you or your child is taking or has recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.

Your doctor may ask you to give your child medicine to lower fever before being given the vaccine. This will help reduce some of the possible side effects of the vaccine.

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

Prevenar 13® can be given concomitantly with the other routine vaccinations given to children of 6 weeks to 5 years old.

Prevenar 13® can be given concomitantly with a seasonal flu vaccine (in adults aged 50 and older).

If you or your child is given more than one vaccine at a time, it is important to be given the vaccines in different areas of the body.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult your doctor before receiving this vaccine.

Driving and using machines
Prevenar 13® is not expected to affect your ability to drive or operate machines. However, some of the side effects mentioned in section 4 “Side effects”, may temporarily affect you. If this happens, wait until the effect has disappeared before driving or using machines.

Important information about some of this medicine’s ingredients
Prevenar 13® contains less than 1 mmol sodium (23 mg) per dose, i.e. 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 preparation.
The dosage and treatment regimen will be determined by your doctor only.

The vaccination schedule for Prevenar 13® will be determined according to the official national immunization guidelines.

This vaccine will be given to you by a doctor or nurse by injection into a muscle, usually in the upper arm or thigh.

Your doctor or nurse will tell you when you or your child should come back for the next dose.
If you or your child has missed a scheduled vaccine, it is important that you make another appointment.
Make sure you or your child completes the course of vaccinations.

Do not exceed the recommended dose.

Adhere to the treatment as recommended by your doctor.

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

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 13® may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Side effects in infants and children (6 weeks to 5 years of age):

Very common side effects (these may occur with more than 1 in 10 doses):
- decreased appetite
- fever; irritability; pain, tenderness, redness, swelling or hardness at the injection site; drowsiness; restless sleep
- redness, hardness, and swelling of 2.5 cm - 7.0 cm at the injection site (after the booster dose, and in children aged 2-5 years old)

Common side effects (these may occur with up to 1 in 10 doses):
- vomiting, diarrhea
- fever of more than 39°C; tenderness at the injection site interfering with movement; redness, hardness, and swelling of 2.5 cm - 7.0 cm at the injection site (after the initial course of injections)
- rash

Uncommon side effects (these may occur with up to 1 in 100 doses):
- seizures (or fits), including those caused by a high fever
- hives (urticaria or urticaria-like rash)
- redness, hardness and swelling of over 7 cm at the injection site; crying

Rare side effects (these may occur with up to 1 in 1,000 doses):
- collapse or shock-like state

- allergic (hypersensitivity) reaction, including swelling of the lips and/or face; difficulty in breathing

Side effects in children and adolescents (6 to 17 years of age):

Very common side effects (these may occur with more than 1 in 10 doses):
- decreased appetite
- irritability; pain, tenderness, redness, swelling or hardness at the injection site; drowsiness; restless sleep; tenderness at the injection site interfering with movement

Common side effects (these may occur with up to 1 in 10 doses):
- headache
- vomiting, diarrhea
- rash, hives (urticaria or urticaria-like rash)
- high fever

Children and adolescents with either HIV infection, sickle cell anemia or a bone-marrow transplant have similar side effects; however, the frequency of the following side effects is very common: headache, vomiting, diarrhea, fever, fatigue, joint and muscle pain.

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

Side effect in adults:

Very common side effects (these may occur with more than 1 in 10 doses):
- decreased appetite, headache, diarrhea; vomiting (for those 18 to 49 years of age)
- chills; tiredness; rash; pain, redness, swelling, hardness or tenderness at the injection site interfering with arm movement (severe pain or tenderness at injection site for those 18-39 years of age and severe limitation of arm movement for those 18 to 39 years of age)
- new or worsening pain in joints, new or worsening pain in muscles
- high fever (for those 18 to 29 years of age)

Common side effects (these may occur with up to 1 in 10 doses):
- vomiting (for those 50 years and older), fever (for those 30 years and older)

Uncommon side effects (these may occur with up to 1 in 100 doses):
- nausea
- allergic (hypersensitivity) reaction, including swelling of the face and/or lips, difficulty in breathing
- enlarged lymph nodes or glands (lymphadenopathy) near the injection site, such as under the arm

Adults with HIV infection have similar side effects; however, the frequency is very common for fever, vomiting and common for nausea.

Adults with a bone marrow transplant have similar side effects; however, the frequency is very common for fever and vomiting.

The following side effects have been reported post-marketing:
- severe allergic reaction including anaphylactic shock; angioedema (swelling of lips, face or throat)

- hives (urticaria), redness and irritation (dermatitis), and itching (pruritus) at the vaccination-site; flushing
- enlarged lymph nodes or glands (lymphadenopathy) near the vaccination-site, such as under the arm or in the groin
- a rash causing itchy red blotches (erythema multiforme).

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 the refrigerator (2°C-8°C). Do not freeze.
- Prevenar 13® is stable for 4 days when stored at a temperature of up to 25°C. At the end of this period the medicine should be used or discarded. This information is for health care professionals only.
- Before injecting shake well to obtain a homogenous 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 13® is available as a white suspension, provided in a pre-filled single-dose syringe (0.5 ml).
Packs contain 1, 5, 10 or 50 pre-filled syringes with or without needle.

Not all pack sizes may be marketed.

Registration holder's name 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:

143-54-33058

Revised in January 2021 according to MOH guidelines.

The following information is intended for medical or healthcare professionals only:

During storage, a white deposit and clear supernatant may be observed. This does not constitute a sign of deterioration.

Inspect visually for any foreign particulate matter and/or abnormal physical appearance; do not use the vaccine if either are found.

Shake well prior to use to obtain a homogeneous white suspension.

Administer the entire dose.

Prevenar 13® is for intramuscular use only. Do not administer intravascularly.

Prevenar 13® must not be mixed with any other vaccines in the same syringe.

Prevenar 13® can be given at the same time as other childhood vaccines; in this case, different vaccination sites should be used.

Prevenar 13® may be given to adults aged 50 years and older at the same time as the trivalent or quadrivalent inactivated influenza vaccine.

Prevenar 13® is stable at temperature up to 25^0C for 4 days. After the end of this period Prevenar 13® should be used or discarded.

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