Package Leaflet: Information for the user

Prevenar 20 suspension for injection
pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed)

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you receive this vaccine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This vaccine has been prescribed for you only. Do not pass it on to others.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Prevenar 20 is and what it is used for

Prevenar 20 is a pneumococcal vaccine given to **individuals from 6 weeks of age and older** to help prevent diseases such as meningitis (inflammation around the brain), sepsis or bacteraemia (bacteria in the blood stream), pneumonia (lung infection) and otitis media (an ear infection) caused by 20 types of the bacteria *Streptococcus pneumoniae.*

Prevenar 20 provides protection against 20 types of *Streptococcus pneumoniae* bacteria.

The vaccine works by helping the body to make its own antibodies, which protect you against these diseases.

2. What you need to know before you or your child receive Prevenar 20

Prevenar 20 should not be given
- if you or your child are allergic (hypersensitive) to the active substances or to any of the other ingredients in this medicine (listed in section 6), or to any other vaccine that contains diphtheria toxoid.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before the vaccination if you or your child:
- have any present or past medical problems 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 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 (such as due to HIV infection); you may not get the full benefit from Prevenar 20,

- your baby was born prematurely; there is a higher risk of apnoea (temporarily stopping breathing) when vaccines are given to babies born prematurely.

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

Other medicines/vaccines and Prevenar 20

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

In adults, Prevenar 20 can be given at the same time as the COVID-19 mRNA vaccine.

Tell your doctor, pharmacist or nurse if you or your child are taking, have recently taken or might take any other medicines, or have recently received any other vaccine.

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

Driving and using machines
Prevenar 20 has no or negligible influence on the ability to drive and use machines. However, some of the effects mentioned under section 4 "Possible side effects" may temporarily affect the ability to drive or use machines.

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

3. How Prevenar 20 is given

The doctor or nurse will inject the recommended dose (0.5 mL) of the vaccine into a muscle in the upper arm or thigh muscle. Other vaccines (including other routine adult and childhood vaccines) may be given at the same time, but not at the same injection site.

Babies and young children up to 2 years: The total number of injections required depends on how old your child is when they receive the first dose of Prevenar 20. Normally, your child will receive either three or four doses of the vaccine, at least 4 weeks apart, starting at 6 weeks to 2 months of age. Four is the maximum number of doses required. Each dose will be given on a separate occasion. Your doctor or nurse will tell you the correct vaccination schedule for your child. It is important to follow the instructions from the doctor or nurse so that your child completes the course of injections.

Premature infants: Your child will receive an initial course of three injections. The first injection may be given as early as six weeks of age with at least one month between doses. A fourth (booster) injection is recommended at approximately 12 months of age.

Children 2 - 17 years and adults: One single dose.

Special populations: Individuals considered to be at a higher risk of pneumococcal infection may receive at least one dose of Prevenar 20. Your doctor will advise the appropriate vaccination schedule.

Tell your doctor, pharmacist or nurse if you have been given a pneumococcal vaccine before.

If you have any further questions on the use of Prevenar 20, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

Serious side effects of Prevenar 20
Tell your doctor immediately if you notice signs of the following serious side effects (see also section 2):

- swelling of the face, lips, mouth, tongue or throat (oedema), shortness of breath (dyspnoea), wheezing (bronchospasm) – these may by signs of a severe allergic reaction such as anaphylaxis, including shock.
- Temperature higher than 39°C in babies or young children.
- A seizure or convulsion, which may be accompanied by a very high temperature. Symptoms may include rapid uncontrollable shaking of the body, loss of muscle control, drooling, sudden changes in mood or behaviour.
- Your child is pale, limp and does not respond to you.

Other side effects

The following side effects include those reported for Prevenar 20 in infants and children (6 weeks to less than 5 years of age):

Very common: may occur with more than 1 in 10 doses of the vaccine

- Decreased appetite.
- Irritability.
- Drowsiness or increased sleep.
- Fever.
- Redness, hardness or swelling, pain or tenderness at the injection site.
- Redness, hardness or swelling of greater than 2.0 to 7.0 cm at the injection site after the booster dose and in children 2 to 5 years of age.

Common: may occur with up to 1 in 10 doses of the vaccine

- Diarrhoea.
- Vomiting.
- Rash.
- Fever (greater than 38.9 °C).
- Redness, hardness or swelling of greater than 2.0 to 7.0 cm at the injection site after the initial course of injections.
- Pain or tenderness interfering with movement at the injection site.

Uncommon: may occur with up to 1 in 100 doses of the vaccine

- Hives (urticaria or urticaria-like rash).
- Redness, hardness or swelling of greater than 7.0 cm at the injection site.

Rare: may occur with up to 1 in 1,000 doses of the vaccine

- Injection-site allergic (hypersensitivity) reaction.

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

- Restless sleep or decreased sleep.
- Crying.

The following side effects include those reported for Prevenar 20 in children and adolescents (5 to less than 18 years of age):

Very common: may occur with more than 1 in 10 doses of the vaccine

- Headache.
- Muscle pain.
- Tiredness.
- Redness, hardness or swelling, pain or tenderness at the injection site.

Common: may occur with up to 1 in 10 doses of the vaccine
- Joint pain.
- Pain or tenderness interfering with movement at the injection site.

Uncommon: may occur with up to 1 in 100 doses of the vaccine
- Hives (urticaria or urticaria-like rash).
- Fever.

The following side effects were seen with Prevenar 13 and may also be seen with Prevenar 20:
- Decreased appetite.
- Irritability.
- Feeling sleepy.
- Restless sleep/decreased sleep.
- Vomiting.
- Diarrhoea.
- Rash.

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

The following side effects were seen with Prevenar 13 in postmarketing experience in children and may also be seen with Prevenar 20:
- Severe allergic reaction including shock (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).

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

Very common: may occur with more than 1 in 10 doses of the vaccine
- Headache.
- Joint pain and muscle pain.
- Tiredness.
- Pain or tenderness at the injection site.

Common: may occur up to 1 in 10 doses of the vaccine
- Fever.
- Redness, hardness or swelling at the injection site.

Uncommon: may occur up to 1 in 100 doses of the vaccine
- Allergic (hypersensitivity) reaction including swelling of the face and/or lips, shortness of breath and trouble breathing.
- 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 or hives (urticaria) at the injection site.
- Swollen glands in the neck, armpit or groin (lymphadenopathy).

- Chills.

The following side effects were seen with Prevenar 13 and may also be seen with Prevenar 20:
- Decreased appetite.
- Pain or tenderness interfering with movement at the injection site.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Prevenar 20

Keep this medicine out of the sight and reach of children.

Do not use this medicine 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.

Store in a refrigerator (2 °C to 8 °C).
Prevenar 20 should be used as soon as possible after being removed from refrigeration.
Do not freeze. Discard if vaccine has been frozen.

Stability data indicate that the vaccine 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 these time periods Prevenar 20 should be used or discarded. These data are intended to guide healthcare professionals in case of temporary temperature excursion only.

Pre-filled syringes should be stored in the refrigerator horizontally to minimise the resuspension time.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Prevenar 20 contains
The active substances are polysaccharide CRM_{197} conjugates consisting of:
- 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.

One dose (0.5 mL) contains approximately 51 micrograms CRM_{197} carrier protein, adsorbed on aluminium phosphate (0.125 mg aluminium).

The other ingredients are sodium chloride, succinic acid, polysorbate 80 and water for injections.

What Prevenar 20 looks like and contents of the pack
The vaccine is a white suspension for injection, provided in a single-dose, pre-filled syringe (0.5 mL). It is provided in pack sizes of 1, 10 and 50, with or without needles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Pfizer Limited
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom

Manufacturer responsible for batch release:
Pfizer Manufacturing Belgium NV
Rijksweg 12
2870 Puurs-Sint-Amands
Belgium

For any information about this medicine, please contact:
Medical Information, Pfizer Ltd, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS.
Telephone 01304 616161.

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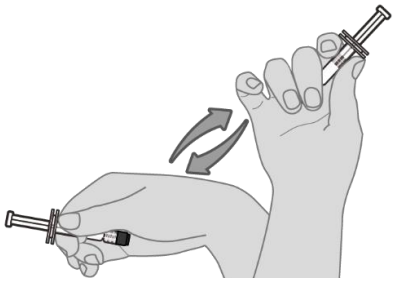
Ref: PE 6_1

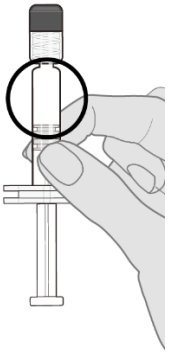
The following information is intended for healthcare professionals only:

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.

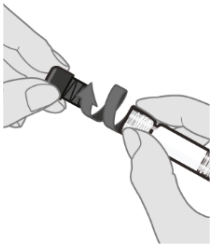
<u>Preparation for administration</u>

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 homogeneous 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/medicinal products in the same syringe.

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