Package Leaflet: Information for the user

Apexxnar 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 Apexxnar is and what it is used for

Apexxnar is a pneumococcal vaccine given to:
- **individuals aged 18 years and older** to help prevent disease such as: pneumonia (lung infection), sepsis or bacteraemia (bacteria in the blood stream) and meningitis (inflammation around the brain) caused by 20 types of the bacteria *Streptococcus pneumoniae.*

Apexxnar 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 receive Apexxnar

Apexxnar should not be given
- if you 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:
- have any present or past medical problems after any dose of Apexxnar 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 Apexxnar.

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

Other medicines/vaccines and Apexxnar
Apexxnar 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 health care provider, separation of both vaccinations of e.g., 4 weeks might be advised.

Apexxnar can be given at the same time as the COVID-19 mRNA vaccine.

Tell your doctor, pharmacist or nurse if you 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
Apexxnar 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.

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

3. How Apexxnar is given

The doctor or nurse will inject the recommended dose (0.5 mL) of the vaccine into your arm.

You should receive 1 injection.

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 Apexxnar, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

Serious side effects
Tell your doctor immediately if you notice signs of the following serious side effect (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.

Other side effects

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

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

- Swelling at injection site, redness at injection site and fever.

Uncommon: may occur up to 1 in 100 doses of the vaccine
- 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 injection site, swollen glands in the neck, armpit or groin (lymphadenopathy), hives at the injection site (urticaria), and chills.

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

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 Apexxnar

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).
Apexxnar 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 Apexxnar 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 Apexxnar 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 Apexxnar 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:	Manufacturer responsible for batch release:
Pfizer Limited	Pfizer Manufacturing Belgium N.V.
Ramsgate Road	Rijksweg 12
Sandwich, Kent	2870 Puurs
CT13 9NJ	Belgium
United Kingdom	

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

This leaflet was last revised in 10/2023.

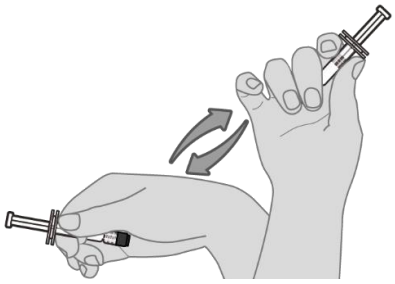
Ref: PE 5_0

The following information is intended for healthcare professionals only:

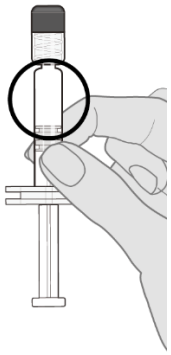
During storage, a white deposit and clear supernatant may be observed. This does not constitute a sign of deterioration. Pre-filled syringes should be stored horizontally to minimise the resuspension time.

<u>Preparation for administration</u>

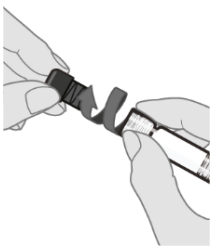
Step 1. Vaccine resuspension
Hold the pre-filled syringe horizontally between the thumb and the forefinger and shake vigorously until the contents of the syringe are a homogeneous white suspension. Do not use the vaccine if it cannot be resuspended.



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.

Apexxnar is for intramuscular use only.

Apexxnar must not be mixed with any other vaccines/medicinal products in the same syringe.

Apexxnar 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 Apexxnar (e.g., by approximately 4 weeks). Different vaccination sites should be used.

Apexxnar 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.