PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

PREVENAR 20, suspension for injection

Pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed)

Sugar-free

Read all of this leaflet carefully before you or your child receive PREVENAR 20

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- PREVENAR 20 has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

Prevenar 20 is a pneumococcal vaccine given to:

- children from 6 weeks to less than 18 years of age to help prevent diseases such as meningitis (inflammation around the brain), sepsis or bacteraemia (bacteria in the blood stream), pneumonia (lung infection) and ear infections (acute otitis media) caused by 20 types of the bacteria *Streptococcus pneumoniae*

- 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*

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

PREVENAR 20 works by helping the body to make its own antibodies, which protect you or your child 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.

Talk to your doctor, pharmacist, or nurse before the vaccination 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 will not protect all persons who are vaccinated.

PREVENAR 20 will only protect against ear infections caused by the types of *Streptococcus pneumoniae* for which the vaccine has been developed. It will not protect against other infectious agents that can cause ear infections.

Other medicines /vaccines and PREVENAR 20

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

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 health care 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 breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider 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 may temporarily affect the ability to drive or use machines.

It is not always possible to predict to what extent PREVENAR 20 may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which PREVENAR 20 affects them.

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

A doctor or a nurse will give the PREVENAR 20 injection. The dose is 0,5 mL injected into a muscle in the upper arm or thigh muscle. Other vaccines (including other routine adult and childhood vaccines) might be given at the same time, but not at the same injection site.

Babies and young children up to 5 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.

- The first injection may be given as early as 6 weeks to 8 weeks of age.
- Each injection will be given on a separate occasion with an interval of at least 4 weeks between doses except for the last injection (booster dose), which will be given between 11 and 15 months of age.

Four is the maximum number of doses required. Each dose will be given on a separate occasion.

Your doctor or clinic nurse will tell you the correct vaccination schedule for your child. It is important to follow the instructions from the doctor or clinic nurse so that your child completes the course of injections.

Premature infants (born less than 37 weeks of pregnancy)

Your child will receive an initial course of three injections followed by a booster dose. 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 between 11 and 15 months of age.

Unvaccinated infants and children over 7 months to less than 12 months of age

Infants 7 months to less than 12 months of age should receive three injections. The first two are given with an interval of at least 4 weeks apart. A third injection will be given in the second year of life.

Unvaccinated children 12 months to less than 24 months of age

Children 12 months to less than 24 months of age should receive two injections, given with an interval of at least 8 weeks apart.

Unvaccinated children 2 years to less than 5 years of age

Children 2 years to less than 5 years of age should receive one injection.

Children 15 months to less than 5 years of age previously fully vaccinated with Prevenar 13

Children 15 months to less than 5 years of age previously fully vaccinated with a pneumococcal conjugate vaccine will receive one injection.

Children and adolescents 5 years to less than 18 years of age regardless of prior Prevenar 13 vaccination

Children and adolescents 5 years to less than 18 years of age will receive one injection.

If your child has previously received Prevenar 13, an interval of at least 8 weeks should pass before receiving Prevenar 20.

Adults

Adults should receive one injection.

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

Special populations

Individuals considered to be at a higher risk of pneumococcal infection (such as those with sickle cell disease or HIV infection), including those previously vaccinated with the 23-valent pneumococcal polysaccharide vaccine, may receive at least one dose of PREVENAR 20.

Individuals with a blood-forming stem cell transplant may receive three injections, with the first given at 3 to 6 months after the transplant and with an interval of at least 4 weeks between doses. A fourth injection (booster dose) is recommended 6 months after the third injection

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

If you receive too much PREVENAR 20

A trained doctor or nurse gives this vaccination, so an overdose is unlikely to occur.

4. Possible side effects

PREVENAR 20 can have side effects.

Not all side effects reported for PREVENAR 20 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PREVENAR 20 please consult your health care provider for advice.

Serious side effects

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.

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

Frequent side effects

- Decreased appetite
- Irritability
- Feeling sleepy
- Fever (high temperature of 38,9 °C or higher).
- 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 2 to less than 5 years of age: redness, hardness or swelling of greater than 2,0 to 7,0 cm
- Diarrhoea
- Vomiting

- Rash

Less frequent side effects

- Seizures (or fits), including those caused by a high temperature
- Hives (urticaria or urticaria-like rash)
- At the injection site: redness, hardness or swelling of more than 7,0 cm
- injection site allergic (hypersensitivity) reaction

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

- Collapse or shock-like state (hypotonic-hyporesponsive episode)
- Allergic (hypersensitivity) reaction including swelling of the face and/or lips
- Crying
- Restless sleep

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

Frequent side effects

- Headache
- Muscle pain
- At the injection site: pain, tenderness (interfering with movement), redness, hardness or swelling
- Tiredness
- Joint pain

Less frequent side effects

- Hives (urticaria or urticaria-like rash)
- Fever

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

- Diarrhoea

- Vomiting
- Decreased appetite
- Irritability
- Feeling sleepy
- Restless sleep
- 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 at the injection site: pain or tenderness interfering with movement were very common.

The following side effects were seen with Prevenar 13 in post-marketing 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:

Frequent side effects:

- Headache
- Joint pain and muscle pain
- Pain/tenderness at injection site and tiredness
- Swelling at injection site, redness at injection site and fever

Less frequent side effects:

- 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 PREVENAR 20:

- A rash causing itchy red blotches (erythema multiforme)
- Irritation at injection site
- Decreased appetite
- Limitation of arm movement

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of PREVENAR 20.

You can report any suspected adverse drug reactions associated with the use of the medicine directly to Pfizer via ZAF.AEReporting@pfizer.com.

5. How to store PREVENAR 20

- Store all medicines out of 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).
- Store in the original package in order to protect from moisture.
- 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 providers 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 CRM197 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 CRM197 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 glass syringe (0,5 mL) with a tip cap and a grey plunger stopper. It is provided in pack sizes of 1, 10 and 50, with or without needles [25G x 5/8" (0,5 x 16 mm) needle or 25G x 1″ (0,5 x 25 mm) needle]. Not all pack sizes may be marketed.

Holder of Certificate of Registration

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