FINAL APPROVED

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S2**

PREVENAR 13 MULTIDOSE VIAL (suspension for injection in multidose container)

Pneumococcal polysaccharide conjugate vaccine (13 valent, adsorbed)

Sugar free

Read all of this leaflet carefully before you or your child are given PREVENAR 13 MULTIDOSE VIAL

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What PREVENAR 13 MULTIDOSE VIAL is and what it is used for

PREVENAR 13 MULTIDOSE VIAL is a pneumococcal vaccine given to:

- children from 6 weeks to 17 years to help protect against diseases such as: meningitis (inflammation around the brain), sepsis or bacteraemia (bacteria in the blood stream), pneumonia (lung infection) and ear infections
- adults 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 13 types of the bacteria *Streptococcus pneumoniae.*

PREVENAR 13, provides protection against 13 types of *Streptococcus pneumoniae* bacteria, and replaces Prevenar, which provided protection against 7 types.

The vaccine 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 13 MULTIDOSE VIAL

PREVENAR 13 MULTIDOSE VIAL should not be given

- if you or your child is 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.
- if you or your child has a severe infection with a high temperature (over 38 °C). If this applies to you or your child, then the vaccination will be postponed until you or your child is feeling better. A minor infection, such as a cold, should not be a problem. However, talk to your health care provider.

Warnings and precautions

Talk to your health care provider before the vaccination if you or your child:

- has any present or past medical problems after any 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), you/she/he may not get the full benefit from PREVENAR 13.
- has experienced seizures as medicines to lower fever may need to be taken before PREVENAR 13 is given. If your child should become unresponsive or experience seizures (fits) after the vaccination, please contact your health care provider immediately. See also section 4.

Talk to your health care provider 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. See also section 4.

As with any vaccine, PREVENAR 13 will not protect all persons who are vaccinated.

PREVENAR 13 will only protect against ear infections in children 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 and PREVENAR 13

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

Your doctor may ask you to give your child paracetamol or other medicines that lower fever before PREVENAR 13 is given. This will help to lower some of the side effects of PREVENAR 13.

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

It is not always possible to predict to what extent PREVENAR 13 may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the certain activities until they are aware of the measure to which PREVENAR 13 affects them.

PREVENAR 13 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 13 MULTIDOSE VIAL contains polysorbate 80

PREVENAR 13 MULTIDOSE VIAL contains 0,1 mg of polysorbate 80 per dose. Polysorbates may cause allergic reactions. Tell your health care provider if you or your child has any known allergies.

PREVENAR 13 MULTIDOSE VIAL contains sodium

PREVENAR 13 MULTIDOSE VIAL contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium-free’.

3. How PREVENAR 13 MULTIDOSE VIAL is given

Do not share medicines prescribed for you with any other person.

If you have the impression that the effect of PREVENAR 13 MULTIDOSE VIAL is too strong or too weak, tell your doctor or pharmacist.

How PREVENAR 13 MULTIDOSE VIAL is given

The health care provider will inject the recommended dose (0,5 mL) of the vaccine into your arm or your child's arm or leg muscle.

Infants aged 6 weeks to 6 months of age

Typically, your child should receive an initial course of three injections of the vaccine followed by a booster dose.

- The first injection may be given from the age of six weeks.
- Each injection will be given at least one month apart.
- A fourth injection (booster) will be given between 11 and 15 months of age.
- You will be told when your child should come back for the next injection.

According to official recommendations in your country, an alternative schedule may be used by your healthcare provider. Please speak to your health care provider for more information.

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. Between 11 and 15 months of age, your child will receive a fourth injection (booster).

Unvaccinated infants, children, and adolescents over 7 months of age

- Infants aged 7 to 11 months should receive two injections. Each injection will be given at least one month apart. A third injection will be given in the second year of life.
- Children aged 12 to 23 months should receive two injections. Each injection will be given at least two months apart.
- Children aged 2 to 17 years should receive one injection.

Infants, children, and adolescents previously vaccinated with PREVENAR

- Infants and children who have previously received Prevenar may receive PREVENAR 13 to complete the course of injections.
- For children **1 to 5 years** of age previously vaccinated with Prevenar, your health care provider will recommend how many injections of PREVENAR 13 are required.

- Children and adolescents **6 to 17 years** of age should receive one injection.

It is important to follow the instructions from the health care provider so that your child completes the course of injections.

If you forget to go back at the scheduled time, ask the health care provider for advice.

Adults

Adults should receive one injection.

Tell your health care provider if you have been given a pneumococcal vaccine before.

If you have any further questions on the use of PREVENAR 13, ask your health care provider.

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 13.

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 1 month between doses. A fourth injection (booster) is recommended 6 months after the third injection.

If you receive more PREVENAR 13 than you should

Since a health care provider will administer PREVENAR 13 he/she will control the dosage. However, in the event of overdosage your health care provider will manage the overdosage.

If you forget to receive the PREVENAR 13 vaccine

Since a health care provider will administer PREVENAR 13, it is unlikely that the dose will be missed

If you have any further questions on the use of this medicine, ask your health care provider.

4. Possible side effects

PREVENAR 13 can have side effects, although not everybody gets them.

Not all side effects reported for PREVENAR 13 are included in this leaflet. Should your general health worsen or if you experience any untoward effects during or after receipt of PREVENAR 13, please consult your health care provider for advice.

Tell your health care provider if you notice any of the following:

The following side effects include those reported for PREVENAR 13 in infants and children (6 weeks to 5 years of age)

Frequent side effects:

- Decreased appetite
- Fever; irritability; pain, tenderness, redness, swelling or hardness at the vaccination-site; drowsiness; restless sleep
- Redness, hardness, swelling at the vaccination-site of 2,5 cm -7,0 cm (after the booster dose and in older children [aged 2 to 5 years])

Less frequent side effects:

- Seizures (or fits), including those caused by a high temperature
- Vomiting; diarrhoea
- Redness, swelling, or hardness at the vaccination-site of more than 7 cm; crying

Other side effects:

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

The following side effects include those reported for PREVENAR 13 in children and adolescents (6 to 17 years of age)

Frequent side effects:

- Decreased appetite
- Irritability; pain, tenderness, redness, swelling or hardness at the vaccination-site; drowsiness; restless sleep; tenderness at the vaccination-site interfering with movement
- Headaches
- Vomiting; diarrhoea
- Rash; hives (urticaria or urticaria-like rash)
- Fever

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 headaches, vomiting, diarrhoea, fever, fatigue, joint and muscle pain were very common.

In babies born very prematurely (at or before 28 weeks of gestation), longer gaps than normal between breaths may occur for 2 - 3 days after vaccination.

The following side effects include those reported for PREVENAR 13 in adults

Frequent side effects:

- Decreased appetite
- Headaches
- Diarrhoea; vomiting (for those 18 to 49 years of age)
- Rash
- Chills; tiredness; rash; pain, redness, swelling hardness or tenderness at the vaccination-site, interfering with arm movement (severe pain or tenderness at vaccination-site for those 18-39 years of age and severe limitation of arm movements for those 18 to 39 years of age)
- Worsening or new pain in your joints, worsening or new pain in your muscles
- Fever (for those 18 to 29 years of age)

Less Frequent side effects:

- Nausea
- Allergic (hypersensitivity) reaction, including swelling of the face and/or lips, difficulty in breathing
- Enlarged lymph nodes or glands (lymphadenopathy) near the vaccination-site, such as under the arm

Adults with HIV infection had similar side effects however the frequencies were very common for fever, vomiting and common for nausea.

Adults with a blood-forming stem cell transplant had similar side effects however the frequencies were very common for fever and vomiting.

Post-marketing side effects:

- Enlarged lymph nodes or glands (lymphadenopathy) near the vaccination-site, such as under the arm or in the groin
- Severe allergic reaction including shock (cardiovascular collapse); angioedema (swelling of lips, face or throat)
- A rash causing itchy red blotches (erythema multiforme)
- Hives (urticaria), redness and irritation (dermatitis) and itching (pruritus) at the vaccination-site; flushing

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. 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 13 MULTIDOSE VIAL.

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 13 MULTIDOSE VIAL

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 ºC – 8 ºC).

Do not freeze.

After first use, the vaccine may be stored in a refrigerator for a maximum of 28 days.

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 13 MULTIDOSE VIAL contains

The active substances are polysaccharide CRM_{197} conjugates consisting of:

- 2,2 µg of polysaccharide for serotypes 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19A, 19F and 23F
- 4,4 µg of polysaccharide for serotype 6B

1 dose (0,5 mL) contains approximately 32 µg CRM197 carrier protein, adsorbed on aluminium phosphate (0,125 mg aluminium).

The other ingredients are:

Sodium chloride

Succinic acid

Polysorbate 80

2- phenoxyethanol

Water for injections

What PREVENAR 13 MULTIDOSE VIAL looks like and contents of the pack

The vaccine is a white suspension for injection, provided in a multidose container (4 x 0,5 mL doses).

Pack sizes of 1, 5, 10, 25 and 50 clear vials.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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