Read the entire leaflet carefully before your child receives this vaccine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If any of the side-effects gets serious, or if you notice any side-effects not listed in this leaflet, please tell your doctor or pharmacist.
- This vaccine has been prescribed for your child. It should not be used in other children.

SCHEDULING STATUS:

S2

PROPRIETARY NAME (and dosage form):

PREVENAR 13® (Ready-to-use Suspension for Injection)

WHAT THIS MEDICINE CONTAINS:

Each 0,5 ml dose of PREVENAR 13 contains:

The active substances:

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

Each serotype is individually conjugated to non-toxic diphtheria CRM_{197} carrier protein and adsorbed on aluminium phosphate.

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

WHAT THIS MEDICINE IS USED FOR:

The vaccine is a ready-to-use suspension for injection and is provided in a single dose pre-filled syringe (0,5 ml).

PREVENAR 13 is a pneumococcal vaccine. PREVENAR 13 helps protect you or your child against diseases such as meningitis, sepsis or bacteraemia (bacteria in blood stream), pneumonia and ear infection caused by thirteen types of the bacteria *Streptococcus pneumoniae.*

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

BEFORE TAKING THIS MEDICINE:

Do not use PREVENAR 13:

If you or your child is allergic (hypersensitive) to the active substances, to any other ingredients, or to any other vaccine that contains diphtheria toxoid.

Take special care with PREVENAR 13:

- If you or your child has any present or past medical problems after any dose of Pneumococcal 7-valent conjugate vaccine (PREVENAR) or PREVENAR 13.
- If you or your child is sick with a high fever.
- If you or your child has any bleeding problems or is receiving treatment with anticoagulant therapy (medicines that reduce the ability of the blood to clot).
- If you or your child has a weakened immune system (for example, due to cancer or kidney disease).

As with any vaccine, PREVENAR 13 will not protect 100 % of people who receive the vaccine. PREVENAR 13 will only protect against disease caused by the serotypes of *Streptococcus pneumoniae* covered by the vaccine.

Using other medicines/vaccines:

Please inform your doctor, nurse or pharmacist if your child is taking, has recently taken any other medicines, including medicines obtained without prescription, or has recently received any other vaccine.

Paracetamol may reduce the effect of PREVENAR 13 in children. The clinical significance of this is not known.

HOW TO TAKE THIS MEDICINE:

The doctor or nurse will inject the recommended dose (0,5 ml) of the vaccine into your child's thigh or your arm or leg muscle.

Infants, children and adolescents 6 weeks to 17 years of age:

Typically, your child should receive four doses of the vaccine. However, the number of required doses will vary, depending on age and previous vaccinations. Each dose will be given on a separate occasion. It is important to follow the instructions from the doctor/nurse so that your child completes the correct course of injections.

PREVENAR 13 can be given at the same time as other childhood vaccines; in this case, different injection-sites should be used.

If you forget to go back to the doctor or nurse at the scheduled time, ask the doctor or nurse for advice. If you have any further questions on the use of PREVENAR 13 ask your doctor.

Adults aged 18 years and older: PREVENAR 13 is to be administered as a single dose to adults 18 years and older including those previously vaccinated with a pneumococcal polysaccharide vaccine.

The need for re-vaccination with a subsequent dose of PREVENAR 13 has not been established. For specific guidelines, please refer to local recommendations.

SIDE-EFFECTS:

PREVENAR 13 is a vaccine that adds protection against six more types of *Streptococcus pneumoniae* bacteria to the pneumococcal 7-valent conjugate vaccine, which has been registered for use since 2003.

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 while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

The following side effects include those reported for PREVENAR 13 in infants and children aged 6 weeks to 5 years:

Frequent side-effects are listed below:

- Decreased appetite
- Irritability
- Drowsiness/increased sleep, restless sleep/decreased sleep
- Fever; any pain, tenderness, redness, swelling or hardness at the injection-site
- Diarrhoea, vomiting
- Rash
- Fever > 39 °C, tenderness at the injection-site interfering with movement

Less frequent side-effects are listed below:

- Crying
- Seizures
- Rash (with or without hives or itchy red blotches)*
- Hypotonic-hyporesponsive episode (collapse or shock-like state)*
- Allergic reaction including swelling of the face and/or lips, difficulty in breathing
- Enlarged lymph nodes (lymphadenopathy) in the region of the injection site*
- Redness, swelling, itching or hives at the injection-site*

* Side effects identified from post-marketing reports

The following side effects include those reported for PREVENAR 13 in children and adolescents aged 5 to 17 years:

Frequent side-effects are listed below:

- Decreased appetite
- Irritability
- Drowsiness/increased sleep; restless, sleep/decreased sleep
- Headache
- Diarrhoea; vomiting
- Rash (with or without hives)
- Tenderness (including impaired movement), pain, redness, swelling or hardness at the injection-site
- Fever

Less frequent side-effects are listed below:

- Enlarged lymph nodes (lymphadenopathy) in the region of the injection-site*
- Anaphylactic/anaphylactoid reaction including shock (cardiovascular collapse)*
- Rash with itchy red blotches*
- Redness, swelling, itching or hives at the injection-site*

* Side effects identified from post-marketing reports

The following side effects include those reported for PREVENAR 13 in adults aged 18 years and older:

Frequent side-effects are listed below

- Decreased appetite
- Headache
- Diarrhoea, vomiting
- Rash

- Pain or aggravation of existing pain in joints or muscles
- Chills, fatigue, any pain, tenderness, redness, swelling or hardness at the injection site; limitation of arm movement
- Fever

Less frequent side-effects are listed below

- Nausea
- Allergic reaction including swelling of the face and/or lips, difficulty breathing
- Enlarged lymph nodes (lymphadenopathy) in the region of the injection-site*
- Anaphylactic/anaphylactoid reaction including shock (cardiovascular collapse)*
- Rash with itchy red blotches*
- Redness, swelling, itching or hives at the injection-site*

* Side effects identified from post-marketing reports.

In babies born very prematurely (at or before 28 weeks after gestation), longer gaps than normal between breaths may occur for 2-3 days after vaccination. The need for monitoring in a hospital for at least 48 hours after vaccination should be considered for very premature infants (born ≤ 30 weeks of gestation).

Please speak to your doctor or pharmacist should you have any questions or concerns. If any of the side-effects gets serious, or if you notice any side-effects not listed in this leaflet, please tell your doctor or pharmacist.

STORAGE AND DISPOSAL INFORMATION:

Keep out of reach and sight of children.

Store at 2°C – 8°C (in a refrigerator). Do not freeze.

Gently shake the vaccine before administration to ensure a uniform suspension of particles.

Do not use PREVENAR 13 after the expiry date stated on the carton and label. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

PRESENTATION:

PREVENAR 13 is a white suspension for injection and provided in a single-dose transparent glass pre-filled syringe (0,5 ml)

Pack sizes of 1 and 10 with or without needles, and a multi pack of 5 packs of 10 transparent 0,5 ml glass pre-filled syringes with or without needles.

IDENTIFICATION OF THE MEDICINE:

After shaking, the vaccine is a white homogenous suspension.

REGISTRATION NUMBER/REFERENCE NUMBER:

PREVENAR 13: 44/30.1/0002

THE NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Pfizer Laboratories (Pty) Ltd.

85 Bute Lane

Sandton

2196

South Africa

THE DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

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