Your doctor is the best resource for medical advice and information. The health information contained herein is provided for educational / awareness purposes only and is not intended to replace discussions with a medical practitioner and/or medical advice or be construed as a promotional information.

Package Leaflet: Information for the user Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P., 13-valent Pre-filled syringe, single dose vial and multidose vial PREVENAR 13®

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- If you have any further questions, ask your doctor.
- This vaccine has been prescribed for you or your child only. Do not pass it on to others.
- If you or your child get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Prevenar 13 (Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P., 13 valent) is and what it is used for
2. What you need to know before you or your child receives Prevenar 13 (Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P., 13 valent)
3. How Prevenar 13 (Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P., 13 valent) is given
4. Possible side effects
5. How to store Prevenar 13 (Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P., 13 valent)
6. Contents of the pack and other information

1. What Prevenar 13 (Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P., 13 valent) is and what it is used for

Prevenar 13 (Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P., 13 valent) is a pneumococcal vaccine given:

- For active immunization for the prevention of disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F (including sepsis, meningitis, bacteraemia, pneumonia) and acute otitis media in infants and children from 6 weeks to 5 years of age.

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- For active immunization for the prevention of Pneumonia and invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F in children of 6 years to 17 years of age.
- For active immunization for the prevention of Pneumonia and invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F in adults of 18 years to 49 years of age.
- For active immunization for the prevention of Pneumonia and invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F in adults of 50 years and older age group.

2. What you need to know before you or your child receives Prevenar 13 (Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P., 13 valent)

Prevenar 13 (Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P., 13 valent) 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 acute 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 doctor first.

Warnings and precautions

Talk to your doctor before the vaccination if you or your child:

- Has any present or past medical problems after any dose of Prevenar 13 (Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P., 13 valent) 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 (Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P., 13 valent).
- Has experienced seizures, as medicines to lower fever may need to be taken before Prevenar 13 (Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P., 13 valent) is given. If your child should become unresponsive or experience seizures (fits) after the vaccination, please contact your doctor immediately. See also section 4.

Talk to your doctor 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 (Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P., 13 valent) will not protect all persons who are vaccinated.

Prevenar 13 (Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P., 13 valent) 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/vaccines and Prevenar 13 (Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P., 13 valent)

Tell your doctor if you or your child is taking, has recently taken or might take any other medicines, or has recently received any other vaccine.

Infants and children aged 6 weeks to 5 years

Prevenar 13 (Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P., 13 valent) can be given concomitantly with any of the following vaccine antigens, either as monovalent or combination vaccines: diphtheria, tetanus, acellular or whole-cell pertussis, *Haemophilus influenzae* type b, inactivated poliomyelitis, hepatitis B, meningococcal serogroup C, measles, mumps, rubella, varicella and rotavirus vaccine.

Prevenar 13 (Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P., 13 valent) can also be given concomitantly between 12-23 months with the tetanus toxoid conjugated meningococcal polysaccharide serogroups A, C, W and Y vaccine to children who have been adequately primed with Prevenar 13 (Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P., 13 valent).

Children and adolescents 6 to 17 years of age

No data are currently available regarding concomitant use with other vaccines.

Adults 18 to 49 years of age

No data are available regarding concomitant use with other vaccines.

Adults aged 50 years and older

Prevenar 13 (Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P., 13 valent) may be administered concomitantly with the seasonal trivalent inactivated influenza vaccine (TIV). Prevenar 13 may be given concomitantly with the seasonal quadrivalent inactivated influenza vaccine (QIV). The immune responses to Prevenar 13 were noninferior when Prevenar 13 was given concomitantly with QIV compared to when Prevenar 13 was given alone.

Different injectable vaccines should always be given at different vaccination sites.

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 for advice before receiving this vaccine.

Driving and using machines

Prevenar 13 (Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P., 13 valent) has no or negligible influence on the ability to drive and use machines.

Prevenar 13 (Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P., 13 valent) contains polysorbate 80

This medicinal product contains 0.1 mg of polysorbate 80 per dose. Polysorbates may cause allergic reactions. Tell your doctor if you or your child has any known allergies.

Prevenar 13 (Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P., 13 valent) contains sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium-free'.

3. How Prevenar 13 (Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P., 13 valent) is given

The doctor or nurse 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.
- The gap between the doses can be 4 to 8 weeks.
- A fourth injection (booster) will be given approximately 12-15 months of age.

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 after the one-year birthday, separated from the second dose by at least 2 months.

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.

For children 1 to 5 years of age who are incompletely vaccinated with Prevenar 13 (Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P., 13 valent):

If current age between 12-23 months:

- If 1 dose is taken less than 12 months, two doses at least 2 months apart and separated from the first dose by at least 2 months should be taken
- If 2 or 3 doses are taken less than 12 months, take 1 dose separated from the first dose by at least 2 months.

If current age 24-71 months with incomplete schedule should take 1 dose separated from the first dose by at least 2 months.

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

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

If you forget to go back at the scheduled time, ask the doctor for advice.

Adults (18 years and above)

Adults should receive one injection.
Tell your doctor, if you have been given a pneumococcal vaccine before.
If you have any further questions on the use of Prevenar 13 (Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P., 13 valent), ask your doctor.

Adults 18-49 years of age

One single dose.
The need for revaccination with a subsequent dose of Prevenar 13 has not been established.
Regardless of prior pneumococcal vaccination status, if the use of 23-valent pneumococcal polysaccharide vaccine is considered appropriate, Prevenar 13 should be given first.

Adults 50 years of Age and Older

One single dose.
The need for re-vaccination with a subsequent dose of Prevenar 13 has not been established.
Regardless of prior pneumococcal vaccination status, if the use of 23-valent pneumococcal polysaccharide vaccine is considered appropriate, Prevenar 13 should be given first.

Vaccination Schedule (for Multi Dose Vial (MDV) only)

The immunization schedules for Prevenar 13 should be based on official recommendations.

Primary Immunization Series

Infants aged 6 weeks – 6 months

Three-dose primary series with booster (3+1)
For infants, the recommended immunization series of Prevenar 13 consists of three doses of 0.5 mL each at 6 weeks, 10 weeks and 14 weeks, followed by a fourth (booster) dose of 0.5 mL at 12-15 months of age.

Three-dose primary series without booster (3+0)

When Prevenar 13 is given as part of routine infant immunization program, a series consisting of three doses, each of 0.5 mL may be given. The first dose may be administered at 8 weeks, with a second dose at 12 weeks and the third at 16 weeks.

Two-dose primary series with booster (2+1)

Alternatively, when used as a part of routine infant immunization programs in various countries, Prevenar 13 may also be recommended in a series consisting of three doses, each of 0.5 ml. The doses recommendations may be as follows:

First Dose	Second Dose	Booster Dose
2 months	4 months	11-15 months
6 weeks	14 weeks	9 months

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 (Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P., 13 valent).

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.

4. Possible side effects

Like all vaccines, Prevenar 13 (Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P., 13 valent) can cause side effects, although not everybody gets them.

The following side effects include those reported for Prevenar 13 (Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P., 13 valent) in infants and children (6 weeks to 5 years of age):

The most common side effects (these may occur with more than 1 in 10 doses of the vaccine) are:

- 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])

Common side effects (these may occur with up to 1 in 10 doses of the vaccine) are:

- Vomiting; diarrhoea
- Fever of more than 39°C; tenderness at the vaccination-site interfering with movement, redness, hardness, swelling at the vaccination-site of 2.5 cm -7.0 cm (after the initial course of injections)
- Rash

Uncommon side effects (these may occur with up to 1 in 100 doses of the vaccine) are:

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

Rare side effects (these may occur with up to 1 in 1,000 doses of the vaccine) are:

- Collapse or shock-like state (hypotonic-hyporesponsive episode)
- Allergic (hypersensitivity) reaction, including swelling of the face and/or lips, difficulty in breathing

The following side effects include those reported for Prevenar 13 (Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P., 13 valent) in children and adolescents (6 to 17 years of age):

The most common side effects (these may occur with more than 1 in 10 doses of the vaccine) are:

- Decreased appetite
- Irritability; pain, tenderness, redness, swelling or hardness at the vaccination-site; drowsiness; restless sleep; tenderness at the vaccination-site interfering with movement

Common side effects (these may occur with up to 1 in 10 doses of the vaccine) are:

- 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.

The following side effects include those reported for Prevenar 13 (Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P., 13 valent) in adults:

The most common side effects (these may occur with more than 1 in 10 doses of the vaccine) are:

- Decreased appetite; headaches; diarrhoea; vomiting (for those 18 to 49 years of age)
- 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)

Common side effects (these may occur with up to 1 in 10 doses of the vaccine) are:

- Vomiting (for those 50 years and older); fever (for those 30 years and older)

Uncommon side effects (these may occur with up to 1 in 100 doses of the vaccine) are:

- 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.

The following additional side effects have been seen with Prevenar 13 (Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P., 13 valent) in postmarketing experience:

The following are considered adverse drug reactions for Prevenar 13; because these reactions were derived from spontaneous reports, the frequencies could not be determined and are thus considered as not known.

Blood and lymphatic system disorders
Lymphadenopathy (localised to the region of the vaccination-site)

Immune system disorders
Anaphylactic/anaphylactoid reaction including shock; angioedema

Skin and subcutaneous tissue disorders
Erythema multiforme

General disorders and administration site conditions
Vaccination-site urticaria; vaccination-site dermatitis; vaccination-site pruritus; flushing

5. How to store Prevenar 13 (Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P., 13 valent)

Keep this vaccine out of reach of children.
Store in a refrigerator (2°C – 8°C).
Store in original package.
Do not freeze.
During storage, a white deposit and clear supernatant can be observed. This does not mean the product has deteriorated.
No special requirements for disposal

6. Contents of the pack and other information

What Prevenar 13 (Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P., 13 valent) 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 CRM_{197} carrier protein, adsorbed on aluminium phosphate (0.125 mg aluminium).

The list of excipients include sodium chloride, succinic acid, polysorbate 80, 2-phenoxyethanol (Applicable for Multidose vial only) and water for injections.

What Prevenar 13 (Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P., 13 valent) looks like and contents of the pack

For Pre-filled syringe
0.5 ml suspension for Injection in pre-filled syringe (Type I glass) with a plunger rod (polypropylene) and the syringe packaging includes hypodermic needle.
Pack sizes of 1, 10 and 50.

For Single dose vial
0.5 ml suspension for injection in a vial (Type I glass) with a latex-free grey chlorobutyl rubber stopper and sealed with an aluminum flip-off seal and a polypropylene flip-off cap.
Pack sizes of 1, 5, 10, 25 and 50.

For Multidose dose vial
2 ml (4 x 0.5 ml doses) suspension for injection in a container (Type I glass) with a latex-free grey chlorobutyl rubber stopper and sealed with an aluminum flip-off seal and a polypropylene flip-off cap.
Pack sizes of 1, 5, 10, 25 and 50.

Not all presentation and pack sizes may be marketed.

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