PREVENAR 13®

Pneumococcal polysaccharide conjugate vaccine, 13-valent adsorbed

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Prevenar 13. It does not contain all the available information. It does not take the place of talking to your doctor, clinic nurse or pharmacist.

All vaccinations have benefits and risks. Your doctor or clinic nurse has weighed the risks of you or your child receiving Prevenar 13 against the benefits this vaccination is expected to provide.

If you have any questions about this vaccination, ask your doctor, clinic nurse or pharmacist.

Keep this leaflet. You may need to read it again.

What Prevenar 13 is used for

Prevenar 13 is a vaccine, which is a type of medicine that helps to protect (immunise) people from certain infectious diseases. It does this by preparing the body's defences to fight the infection, before you catch the bacteria or virus.

Prevenar 13 is a mixture of the outer sugar coating (polysaccharide) from 13 different strains or serotypes of bacteria called Streptococcus pneumoniae. Each serotype is joined to a non-toxic protein to make it work more effectively. Streptococcus pneumoniae bacteria are one of the causes of

- meningitis (a serious brain infection that could cause death or brain damage)
- bacteraemia (infection of the blood)
- pneumonia
- otitis media (an ear infection that can cause pain and temporary hearing loss and may require you or your child to have an ear operation).

Prevenar 13 can protect against 13 of the strains of Streptococcus pneumoniae that can cause these diseases. Prevenar 13 does not replace the need for vaccination with Haemophilus influenzae type b (Hib) or meningococcal vaccines that protect against other important causes of meningitis.

You cannot catch any of the above diseases from the vaccine itself, because it is not made with live or whole bacteria.

As with all vaccines, 100% protection against the above diseases cannot be guaranteed.

Before you or your child is given Prevenar 13

When you or your child should not be given Prevenar 13

You or your child should not be given Prevenar 13 if you or your child have ever had an allergic reaction to pneumococcal or diphtheria vaccines, or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Vaccination should be delayed if you or your child have a fever or infection requiring a visit to the doctor.

If you are not sure whether you or your child should be given Prevenar 13, talk to your doctor or clinic nurse. A mild illness without a raised temperature (such as a cold) is not usually a reason to delay vaccination.

Before giving Prevenar 13 make sure that the expiry date (EXP) printed on the pack has not been passed. If it has, use a new pack.

Prevenar 13 is not recommended for babies younger than 6 weeks of age.

Before each Prevenar 13 injection

You must tell the doctor or nurse

- if you suspect or know that you or your child may be allergic to anything, including foods, any medicines or other vaccines
- if you or your child have had a reaction to an earlier dose of Prevenar 13 vaccine
- if you or your child have any bleeding problems
- if you or your child are sick with a high fever
- if you or your child have a previous history of interruption in breathing after any vaccination.

In rare cases, the doctor or nurse may decide that the risk of a further reaction may outweigh the benefits of immunisation.

Tell your doctor if your baby was born prematurely

There is a higher risk of apnoea (temporarily stopping breathing) when vaccines are given to premature babies.

Tell your doctor or clinic nurse if you or your child are having anti-cancer therapy or have an HIV infection or any other condition that affects the immune response.

Prevenar 13 may not be as effective in individuals with reduced immune responsiveness due to various causes such as these.

Tell your doctor or clinic nurse if you or your child have any other disease.

Prevenar 13 may not be suitable for individuals with certain diseases.

Taking other medicines

Tell your doctor or nurse if you or your child are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop, or if you or your child have recently been given any other vaccine.

How Prevenar 13 is given

A doctor or a nurse will give the Prevenar 13 injection. The dose is 0.5 mL injected into a muscle in the thigh or upper arm. Other vaccines might be given at the same time, but not at the same injection site.

How many injections will be given

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 13. Normally, your child will receive either three or four doses of the vaccine, at least 4 weeks apart, starting at 6 weeks to 2 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: 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. A fourth (booster) injection is recommended at approximately 12 months of age.

Children 6 - 17 years and adults: One single dose.

Special populations: Individuals considered to be at a higher risk of pneumococcal infection may receive at least one dose of Prevenar 13. Your doctor will advise the appropriate vaccination schedule.

If your child misses one or more doses

If your child misses one or more doses, talk to your doctor or clinic nurse.

Overdose

A trained doctor or nurse gives this vaccination, so an overdose is unlikely to occur. An overdose would be unlikely to harm you or your child.

Side Effects

Do not be alarmed by this list of possible side effects.

You or your child may not experience any of them.

Tell your doctor or clinic nurse as soon as possible if you or your child are not well after receiving Prevenar 13.

Like all vaccines, Prevenar 13 may cause unwanted side effects All medicines including vaccines, can have side effects. Sometimes they are serious, most of the time they are not. You or your child may need medical treatment for some side effects.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

Common side effects:

- local reaction around the injection site such as redness, itchiness, tenderness, pain or discomfort which may temporarily prevent use of the arm, warmth, burning or stinging, swelling, limitation of arm movement or the formation of hard lumps or scars
- flushing or redness of the skin
- sleepiness
- disturbed sleep
- chills
- fatigue
- irritability
- fever
- headache
- loss of appetite
- vomiting
- diarrhoea

- skin rash, itchy spots or red lumps on the skin, also called hives
- itchiness, hives or rash over the body
- joint or muscle pain

Uncommon side effects:

- crying
- nausea
- swelling of the glands in the neck, armpit or groin

These side effects are usually mild.

If any of the following happen, tell your doctor or pharmacist immediately or go to Accident and Emergency at your nearest hospital:

- allergic reaction such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath or trouble breathing
- a seizure or convulsion, which may be accompanied by a very high temperature. Symptoms may include rapid uncontrollable shaking of the body, loss of muscle control, drooling, sudden changes in mood or behaviour.
- rapid, shallow breathing, cold, clammy skin, a rapid, weak pulse, dizziness, weakness and fainting
- temperature higher than 39°C in babies or young children
- temporary interruptions of breathing. In babies born very prematurely (at or before 28 weeks before gestation), longer gaps than normal between breaths may occur for 2 - 3 days after vaccination
- your child is pale, limp and does not respond to you.

These are very serious side effects. You or your child may need urgent medical attention or hospitalisation.

Other side effects not listed above may occur in some individuals. Tell your doctor or pharmacist if you notice anything that is making you or your child feel unwell.

Ask your doctor or clinic nurse to answer any questions you may have.

After receiving Prevenar 13

Storage

It is unlikely that you will be asked to store Prevenar 13. If you are:

Keep this vaccine in the refrigerator at a temperature between 2°C and 8°C where young children cannot reach it.

Do not freeze it. If the vaccine has been frozen it should not be used.

Keep Prevenar 13 in the original pack until it is time to be given.

Product description

What it looks like

Prevenar 13 is a clear liquid with sediment, which after shaking will look like a white coloured liquid (called a suspension).

Prevenar 13 is supplied as a suspension in 0.5 mL pre-filled syringes in packs of 1 and 10.

Ingredients

Each 0.5 mL dose of Prevenar 13 contains the following active ingredients:

- 30.8 micrograms of pneumococcal purified capsular polysaccharides
- 32 micrograms of CRM197 protein

plus the following inactive ingredients:

- aluminium phosphate
- sodium chloride
- succinic acid
- polysorbate 80
- water for injections

The manufacture of this product includes exposure to bovine derived materials. No evidence exists that any case of vCJD (considered to be the human form of bovine spongiform encephalopathy) has resulted from the administration of any vaccine product.

Supplier

Prevenar 13 is supplied in Australia by:

Pfizer Australia Pty Ltd
Sydney NSW
www.pfizer.com
Toll Free Number: 1800 675 229

Australian registration number

Prevenar 13 pre-filled syringes: AUST R 158450

Date of preparation

This leaflet was prepared in August 2020.

® Registered Trade Mark