

PREVENAR[®]

Pneumococcal conjugate vaccine, 7-valent

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Prevenar. 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 your child receiving Prevenar 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 is used for

Prevenar 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 is usually recommended for use in babies and young children from 6 weeks to 9 years of age. Prevenar is a mixture of the outer sugar coating (polysaccharide) from 7 different strains or serotypes of bacteria called *Streptococcus pneumoniae*. Each serotype is joined to a non-toxic protein to make it work more effectively in babies and young children. Prevenar is not recommended for use in adults or in children older than 9 years of age.

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 your child to have an ear operation).

Prevenar can protect against 7 of the strains of *Streptococcus pneumoniae* that can cause these diseases. Prevenar does not replace the need for vaccination with *Haemophilus influenzae* type b (Hib), a vaccine that protects against another important cause of meningitis.

Your child cannot catch any of the above diseases from the vaccine itself, because it is not made with live or whole bacteria. The chance of a severe reaction from Prevenar is very small and the risks from not being vaccinated with Prevenar can be very serious.

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

Before your child is given Prevenar

When your child should not be given Prevenar

Your child should not have Prevenar if he or she has ever had an allergic reaction to pneumo-coccal or diphtheria vaccines, latex, 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.

The vaccination of your child should be delayed if he/she has a fever or infection requiring a visit to the doctor.

If you are not sure whether your child should be given Prevenar, 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 make sure that the expiry date (EXP) printed on the pack has not been passed. If it has, use a new pack.

Prevenar is not recommended for babies younger than 6 weeks or children older than 9 years.

Before each Prevenar injection

You must tell the doctor or nurse

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

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

Tell your doctor or clinic nurse if your child is having anti-cancer therapy or has an HIV infection or any other condition that affects their immune response.

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

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

Prevenar may not be suitable for all children with certain diseases.

Taking other medications

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

How Prevenar is given

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

How long will your child be having the injections

The total number of injections required depends on how old your child is when they receive the first dose of Prevenar. Normally, your child will receive four doses of the vaccine, at least 4 weeks apart, starting at 6 to 8 weeks 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.

Overdose

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

If your child misses one or more doses

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

Side Effects

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

Your child may not experience any of them.

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

Like all vaccines, Prevenar may cause unwanted side effects in a few children. All medicines have side effects. Sometimes they are serious, most of the time they are not. Your child may need medical treatment for some side effects.

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

- Your child feels pain, discomfort or tenderness at the injection site.
- You notice a rash, redness, swelling or a lump at the injection site.

These side effects usually last for only a few hours and should not require treatment. If your baby or child has any of these side effects after one vaccination, he/she will possibly have the same reaction after the next dose of Prevenar.

If your child has any of these side effects or any unexpected reaction in the 48 hours following vaccination, please contact your doctor or local baby health centre.

Other side effects that may occur are:

- Fever of more than 38 °C.

A single dose of paracetamol may be needed to reduce fever.

- Irritability,
- Drowsiness,
- Restless sleep,
- Decreased appetite,
- Vomiting and diarrhoea.

Tell your doctor immediately or go to accident and emergency at your nearest hospital if you notice your child is experiencing any of the following rare side effects.

- Allergic reaction such as rash, itching, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty in breathing.
- Seizures
- Temporary interruptions in breathing.

In most reported cases of temporary interruptions in breathing, Prevenar was given at the same time as other vaccines. Also, in most cases, there was an existing medical condition such as previous history of interruption in breathing, infection, prematurity and/or seizure.

These are serious side effects. Your child may need urgent medical attention or hospitalisation.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making your child feel unwell. Do not be alarmed by this list of possible side effects. Your child may not experience any of them.

Ask your doctor or clinic nurse if you do not understand anything in this list.

After receiving Prevenar

Storage

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

Keep this vaccine in the refrigerator at a temperature between 2° 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 in the original pack until it is time to be given.

Product description

What it looks like

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

Prevenar is supplied as a suspension in 0.5 mL single-dose glass vials and 0.5 mL pre-filled syringes in packs of 1 and 10.

Ingredients

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

- 16 micrograms of bacterial saccharides
 - 20 micrograms of CRM197 protein
- plus the following inactive ingredients:

- aluminium phosphate
- sodium chloride
- water for injection

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 is supplied by:

Wyeth Australia Pty. Limited

17-19 Solent Circuit, Norwest Business Park, Baulkham Hills, NSW 2153.

ABN 16 000 296 211

Telephone: (02) 9761 8200

For further information please contact Wyeth Australia on toll-free 1800 500 498 or E-mail: medinfo@wyeth.com

Australian registration number:

Vials: AUST R 73585.

Pre-filled syringes: AUST R 118375

Wyeth (NZ) Limited

15B Vestey Drive, Mt Wellington, Auckland, New Zealand

Telephone (09) 573 5100

For further information please contact Wyeth New Zealand on toll-free 0800 447 400 or E-mail: medinfo@wyeth.com

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