

PREVENAR 13®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being given PREVENAR 13?

PREVENAR 13 contains the active ingredient Pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed). PREVENAR 13 is a vaccine, which is a type of medicine that helps to protect (immunise) people from certain infectious diseases.

For more information, see Section [1. Why am I being given PREVENAR 13?](#) in the full CMI.

2. What should I know before I am 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 the CMI. Tell your doctor if you or your child have a fever or infection requiring a visit to the doctor. 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. Tell your doctor or clinic nurse if you child being vaccinated was born prematurely. Tell your doctor if you have any other disease or medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am given PREVENAR 13?](#) in the full CMI.

3. What if I am 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 have recently been given any other vaccine. Some medicines may interfere with PREVENAR 13 and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is PREVENAR 13 given?

- A doctor or nurse will give the PREVENAR 13 injection. The dose is 0.5 mL and is 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.
- Children (6 - 17 years) and adults (18 years and older) are given one single dose. Dosing in children up to 5 years is based on their age.

More instructions can be found in Section [4. How is PREVENAR 13 given?](#) in the full CMI.

5. What should I know after being given PREVENAR 13?

Things you should do	<ul style="list-style-type: none">● Check with your doctor before you receive any other vaccines or medicines.
Driving or using machines	<ul style="list-style-type: none">● Be careful before you drive or use any machines or tools until you know how PREVENAR 13 affects you.● PREVENAR 13 has no negligible effect on your ability to drive and use machines. However, some of the reported adverse reactions may temporarily affect the ability to drive or use machines.
Looking after your medicine	<ul style="list-style-type: none">● It is unlikely that you will be asked to store PREVENAR 13.

- Keep PREVENAR 13 in a refrigerator (2°C to 8°C). Do not freeze.

For more information, see Section [5. What should I know after being given PREVENAR 13?](#) in the full CMI.

6. Are there any side effects?

Like all vaccines, PREVENAR 13 may cause unwanted side effects. Common side effects of PREVENAR 13 are local reactions such as tenderness or pain, redness, swelling or the formation of hard lumps or scars, headache, fatigue, fever, joint or muscle pain. Serious side effects include allergic reactions.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

PREVENAR 13®

Active ingredient(s): *Pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using PREVENAR 13. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All vaccinations have risks and benefits. Your doctor has weighed the risks of you or your child receiving PREVENAR 13 against the benefits they expect it will have for you.

You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using PREVENAR 13.

Read this leaflet carefully before you use PREVENAR 13 and keep it. You may need to read it again.

Where to find information in this leaflet:

- [1. Why am I being given PREVENAR 13?](#)
- [2. What should I know before I am given PREVENAR 13?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is PREVENAR 13 given?](#)
- [5. What should I know after being given PREVENAR 13?](#)

[6. Are there any side effects?](#)

[7. Product details](#)

1. Why am I being given PREVENAR 13?

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 (infection of the lung)
- 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 influenza 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.

Ask your doctor if you have any questions about this vaccine.

2. What should I know before I am given PREVENAR 13?

Warnings

You will not be given PREVENAR 13 if:

- you or your child are allergic to pneumococcal or diphtheria vaccines, or any of the ingredients listed at the end of this leaflet.

Check with your doctor or nurse if:

- you or your child are sick with a high fever
- your baby was born prematurely.

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

- you suspect or know that you or your child may be allergic to anything, including foods, any medicines or other vaccines.

- you or your child have had a reaction to an earlier dose of PREVENAR 13 vaccine or any other pneumococcal vaccine.
- 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.

Medical conditions and treatments

Tell your doctor or nurse if the following medical conditions or treatments apply to you or your child being vaccinated. PREVENAR 13 may not be suitable for individuals with certain diseases.

- you or your child have any bleeding problems.
- 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 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.

During vaccination, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you or your child are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Tell your doctor or nurse if you or your child have recently been given any other vaccine.

4. How is PREVENAR 13 given?

A doctor or 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.

If you are given too much PREVENAR 13

A trained doctor or nurse gives this vaccination, so an overdose is unlikely to occur.

5. What should I know after being given PREVENAR 13?

Things you should do

Check with your doctor before you or your child receive any other vaccines or medicines.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how PREVENAR 13 affects you.

PREVENAR 13 has no negligible effect on your ability to drive and use machines. However, some of the reported adverse reactions may temporarily affect the ability to drive or use machines.

Looking after your medicine

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.

6. Are there any side effects?

All medicines can have side effects. If you or your child do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects

Side effects	What to do
<p>General effects:</p> <ul style="list-style-type: none">• fatigue• fever or chills• irritability• crying <p>Nervous System reactions:</p> <ul style="list-style-type: none">• disturbed sleep• sleepiness• headache <p>Nutritional effects:</p> <ul style="list-style-type: none">• loss of appetite <p>Gastrointestinal effects:</p> <ul style="list-style-type: none">• nausea	<p>Speak to your doctor if you have any of these side effects and they worry you.</p> <p>They are usually mild and short-lived.</p>

Side effects	What to do
<ul style="list-style-type: none"> ● vomiting ● diarrhoea <p>Joints and muscle:</p> <ul style="list-style-type: none"> ● joint or muscle pain <p>Injection site effects:</p> <ul style="list-style-type: none"> ● local reaction around the injection site such as tenderness or pain, redness, rash, itchiness, or swelling or the formation of hard lumps or scars <p>Glandular effects:</p> <ul style="list-style-type: none"> ● swelling of the glands in the neck, armpit or groin 	

Serious side effects

Serious side effects	What to do
<p>Immune reactions:</p> <ul style="list-style-type: none"> ● allergic reactions such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<p>shortness of breath or trouble breathing</p> <ul style="list-style-type: none"> ● rapid, shallow breathing, cold, clammy skin, a rapid, weak pulse, dizziness, weakness and fainting. <p>Other reactions:</p> <ul style="list-style-type: none"> ● temperature higher than 39°C in babies or young children ● 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 ● temporary interruptions of breathing. In babies born very prematurely (at or before 28 weeks before gestation), longer gaps than normal between breaths may 	<p>You may need urgent medical attention or hospitalisation.</p>

Serious side effects	What to do
<p>occur for 2 - 3 days after vaccination</p> <ul style="list-style-type: none"> • your child is pale, limp and does not respond to you. 	

Tell your doctor or pharmacist if you notice anything else that may be making you or your child feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you or your child experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What PREVENAR 13 contains

Active ingredient (main ingredient)	pneumococcal purified capsular polysaccharides diphtheria CRM197 protein
Other ingredients (inactive ingredients)	aluminium phosphate sodium chloride succinic acid polysorbate 80 water for injection

You should not be given this vaccine if you are allergic to any of these ingredients.

What PREVENAR 13 looks like

PREVENAR 13 Pre-filled Syringe (Solution for injection)

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.

(AUST R 158450).

Who distributes PREVENAR 13

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

This leaflet was prepared in July 2025.

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