PREVENAR 20®

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.

▼ This medicine is new or being used in a different way. Please report side effects. See the full CMI for further details.

1. Why am I being given PREVENAR 20?

PREVENAR 20 contains the active ingredient Pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed). PREVENAR 20 is a vaccine, which is a type of medicine. PREVENAR 20 helps to protect (immunise) from certain infectious diseases.

For more information, see Section 1. Why am I getting PREVENAR 20? in the full CMI.

2. What should I know before I am given PREVENAR 20?

Do not use if you have ever had an allergic reaction to pneumococcal or diphtheria vaccines, or any of the ingredients listed at the end of this CMI; Tell your doctor if you have a a fever or infection requiring a visit to the doctor; Tell your doctor or clinic nurse if you 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 your 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 20? in the full CMI.

3. What if I am taking other medicines?

Tell your doctor or nurse if you 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.

For more information, see Section 3. What if I am taking other medicines? in the full CMI.

4. How is PREVENAR 20 given?

- A doctor or a nurse will give the PREVENAR 20 injection. The dose is injected into a muscle in the upper arm or thigh. Other vaccines might be given at the same time, but not at the same injection site.
- Adults (18 years and older) are given one single dose. Dosing in children is based on their age.

More instructions can be found in Section 4. How is PREVENAR 20 given? in the full CMI.

5. What should I know after being given PREVENAR 20?

Things you should do	• Check with your doctor before you 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 20 affects you. • PREVENAR 20 has no or negligible effect on your ability to drive and use machine. However, other side effects may influence your ability to drive, such as fatigue or headache.
Looking after your medicine	• It is unlikely that you will be asked to store PREVENAR 20. • Keep PREVENAR 20 in a refrigerator (2°C to 8°C). Do not freeze.

For more information, see Section 5. What should I know while using PREVENAR 20? in the full CMI.

6. Are there any side effects?

Like all vaccines, PREVENAR 20 may cause unwanted side effects.

Common side effects of PREVENAR 20 are local reaction around the injection site 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.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

PREVENAR 20®

Active ingredient(s): *Pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using PREVENAR 20. 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 this vaccine 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 20.

Read this leaflet carefully before you use PREVENAR 20 and keep. You may need to read it again.

Where to find information in this leaflet:

1. Why am I being given PREVENAR 20?
2. What should I know before I am given PREVENAR 20?
3. What if I am taking other medicines?
4. How is PREVENAR 20 given?
5. What should I know after given PREVENAR 20?
6. Are there any side effects?
7. Product details

1. Why am I being given PREVENAR 20?

PREVENAR 20 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 20 is a mixture of the outer sugar coating (polysaccharide) from 20 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 20 can protect against 20 of the strains of *Streptococcus pneumoniae* that can cause these diseases. PREVENAR 20 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.

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

2. What should I know before I am given PREVENAR 20?

Warnings

Do not use if:

- you or your child are allergic to 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 20 vaccine or any other pneumococcal vaccine.

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 clinic nurse if the following medical conditions or treatments apply to you or your child being vaccinated. PREVENAR 20 may not be suitable for individuals with certain diseases.

- you have any bleeding problems
- you are having anti-cancer therapy or have an HIV infection or any other condition that affects the immune response. PREVENAR 20 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.

During vaccination, you or your child 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 nurse if you or your child are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from a 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 20 given?

A doctor or a nurse will give the PREVENAR 20 injection. The dose is 0.5 mL injected into a muscle in the upper arm or thigh muscle. Other vaccines (including other routine adult and childhood 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 20. 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 20. Your doctor will advise the appropriate vaccination schedule.
- Adults (18 years and older): One single dose

If you use too much PREVENAR 20

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

5. What should I know after being given PREVENAR 20?

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 20 affects you.

PREVENAR 20 has no or negligible effect on your ability to drive and use machine. However, other side effects may influence your ability to drive, such as muscle pain, fatigue or headache.

Looking after your medicine

It is unlikely that you will be asked to store PREVENAR 20. 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 20 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 effect	What to do
General effects: • fatigue • fever or chills • irritability • crying **Nervous System reactions:** • restless sleep or decreased sleep • drowsiness or increased sleep • headache **Nutritional effects:** • decreased appetite **Gastrointestinal effects:** • nausea • vomiting • diarrhoea **Skin reactions:** • rash	**Speak to your doctor if you have any of these side effects and they worry you.** They are usually mild and short-lived.

Side effect	What to do
Joints and muscle: • joint or muscle pain **Injection site effects:** • local reaction around the injection site such as tenderness or pain, redness, rash, itchiness or swelling or formation of hard lumps or scars **Glandular effects:** • swelling of the glands in the neck, armpit or groin	
Immune reactions: • 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 • rapid, shallow breathing, cold, clammy skin, a rapid, weak pulse, dizziness, weakness and fainting **Other reactions:** • 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. • your child is pale, limp and does not respond to you.	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these side effects.** You may need urgent medical attention or hospitalisation.

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.

7. Product details

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

What PREVENAR 20 contains

Active ingredient (main ingredient)	Pneumococcal purified capsular polysaccharides diptheria CRM197 protein
Other ingredients (inactive ingredients)	Aluminium phosphate Sodium chloride Succinic acid Polysorbate 80 Water for injections

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

What PREVENAR 20 looks like

PREVENAR 20 Pre-filled Syringe (Solution for injection)

PREVENAR 20 is a clear liquid with sediment which, after shaking, will look like a white coloured liquid (called a suspension). PREVENAR 20 is supplied as a suspension in 0.5 mL pre-filled syringes in packs of 1 and 10.

(AUST R 376353)

Who distributes PREVENAR 20

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizer.com.au

This leaflet was prepared in January 2024.

® = Registered Trademark