

Consumer Medicine Information (CMI) summary

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

▼ This vaccine is new. Please report side effects that you may experience with this vaccine. See the [full CMI](#) for further details.

1. Why am I being given CAPVAXIVE?

CAPVAXIVE is a vaccine given to adults to help protect against pneumococcal disease and pneumonia caused by bacteria called pneumococcus.

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

2. What should I know before I am given CAPVAXIVE?

Do not get CAPVAXIVE if you are allergic to any of the ingredients in CAPVAXIVE listed at the end of the CMI or diphtheria vaccines.

Talk to your doctor if you have any other medical conditions or any allergies, 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 CAPVAXIVE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CAPVAXIVE and affect how it works. Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other vaccines or medicines including medicines obtained without a prescription.

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

4. How is CAPVAXIVE given?

A doctor or nurse will give you this vaccine as an injection into the muscle.

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

5. What should I know after being given CAPVAXIVE?

Things you should do	<ul style="list-style-type: none">• Call your doctor straight away if you have symptoms of an allergic reaction, which may include wheezing or trouble breathing, swelling of the face, lips or tongue, hives or rash.• Remind any doctor, nurse or pharmacist you visit that you have been given CAPVAXIVE.
Driving or using machines	<ul style="list-style-type: none">• CAPVAXIVE is not likely to affect the ability to drive or use machines.
Looking after your vaccine	<ul style="list-style-type: none">• It is unlikely that you will be asked to store CAPVAXIVE. If you are, keep this vaccine in the refrigerator between 2°C and 8°C. Do not freeze this vaccine.• Keep this vaccine in the original pack until it is time to be given.

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

6. Are there any side effects?

The most common side effects are pain, swelling or redness where you had the injection, feeling tired, headache and muscle aches. A less common side effect is fever. These side effects are generally mild and usually last less than 3 days.

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 vaccine 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.

CAPVAXIVE

Pneumococcal 21-valent Conjugate Vaccine

Consumer Medicine Information (CMI)

This leaflet provides important information about getting CAPVAXIVE. **You should also speak to your doctor, nurse or pharmacist if you would like further information or if you have any concerns or questions about getting CAPVAXIVE.**

Where to find information in this leaflet:

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

1. Why am I being given CAPVAXIVE?

CAPVAXIVE is a vaccine given to adults to help protect against pneumococcal disease caused by bacteria called pneumococcus.

Pneumococcal disease is any illness caused by pneumococcus. These bacteria can cause many types of illnesses, such as infections in:

- your lungs (called pneumonia)
- the area around your brain and spinal cord (called meningitis)
- your blood (called bacteremia)

These illnesses are more likely to happen in people who are older or have health conditions (such as alcoholism, asthma, diabetes, heart problems, HIV (human immunodeficiency virus), liver problems, lung problems, or smoking).

2. What should I know before I am given CAPVAXIVE?

Warnings

Do not get CAPVAXIVE if:

- You are allergic to any of the ingredients in CAPVAXIVE listed at the end of this leaflet, or to diphtheria vaccines.
- Always check the ingredients to make sure you can be given this vaccine.

Check with your doctor if you:

- Have or have had any medical conditions or any allergies.
- Have a weak immune system (which means the body is less able to fight off infections) or are taking certain medicines that may make the immune system weak.

After being given CAPVAXIVE, 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 planning to become pregnant. They will tell you if you should receive CAPVAXIVE.

Talk to your doctor if you are breastfeeding or intend to breastfeed. They will tell you if you should receive CAPVAXIVE.

Children

CAPVAXIVE has not been studied in children who are under 18 years of age.

3. What if I am taking other medicines?

CAPVAXIVE can be given at the same time as flu (inactivated influenza) vaccine.

Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other vaccines or medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor, nurse or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect CAPVAXIVE.

4. How is CAPVAXIVE given?

How CAPVAXIVE is given

- A doctor or nurse will give you this vaccine as an injection into the muscle

How many injections will be given

- Adults (18 years of age and older) need one dose of the vaccine.

5. What should I know after being given CAPVAXIVE?

Things you should do

Call your doctor straight away if you:

- Have symptoms of an allergic reaction, which may include wheezing or trouble breathing, swelling of the face, lips or tongue, hives or rash.

Remind any doctor, nurse or pharmacist you visit that you have been given CAPVAXIVE.

Driving or using machines

CAPVAXIVE is not likely to affect the ability to drive or use machines.

Looking after your vaccine

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

- Keep this vaccine in the refrigerator at a temperature between 2°C and 8°C.
- Do not freeze this vaccine.
- Keep this vaccine in the original pack until it is time to be given.

Keep it where young children cannot reach it.

Getting rid of any unwanted vaccine

It is unlikely that you will be asked to dispose of CAPVAXIVE. However, if you no longer need this vaccine or it is out of date, take it to any pharmacy for safe disposal.

Do not get this vaccine after the expiry date.

6. Are there any side effects?

All medicines, including vaccines, can have side effects. If you 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, nurse or pharmacist if you have any further questions about side effects.

Tell your doctor, nurse or pharmacist about these side effects or any unusual symptoms that develop after you get this vaccine.

Side effects

Side effects	What to do
<p>Most common side effects:</p> <ul style="list-style-type: none"> • Pain, swelling or redness where you had the injection • Feeling tired • Headache • Muscle aches <p>Other less common side effects seen with CAPVAXIVE:</p> <ul style="list-style-type: none"> • Fever <p>These side effects are generally mild and usually last less than 3 days.</p>	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>
<p>As with all vaccines given by injection, there is a very small risk of a serious allergic reaction.</p> <p>Symptoms may include:</p> <ul style="list-style-type: none"> • Wheezing or trouble breathing, • Swelling of the face, lips or tongue • hives • rash 	<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>

Reporting side effects

After you have received medical advice for any side effects you 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 vaccine.

7. Product details

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

What CAPVAXIVE contains

Active ingredient (main ingredient)	Bacterial sugars from 21 types of pneumococcus each linked to a protein (diphtheria CRM197 protein) as the active ingredient*.
Other ingredients	Histidine Polysorbate 20 Sodium chloride Water for injections

*The sugars from these bacteria and the protein are not alive and do not cause disease.

CAPVAXIVE does not contain any preservatives.

Do not get this vaccine if you are allergic to any of these ingredients.

What CAPVAXIVE looks like

CAPVAXIVE is a colourless, clear to opalescent solution for injection.

CAPVAXIVE is available as a prefilled syringe (AUST R 429290).

Who distributes CAPVAXIVE

Merck Sharp & Dohme (Australia) Pty Limited
Level 1, Building A, 26 Talavera Road
Macquarie Park NSW 2113

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