

VAXNEUVANCE®

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 or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I being given VAXNEUVANCE?

VAXNEUVANCE is a vaccine given to help protect you against pneumococcal disease caused by 15 types of bacteria called *Streptococcus pneumoniae* or pneumococcus. VAXNEUVANCE can be given to people 18 years of age and older.

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

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

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

Talk to your doctor if you have any other 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 VAXNEUVANCE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with VAXNEUVANCE 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 am I given VAXNEUVANCE?

- A doctor or nurse will give you this vaccine as an injection into the muscle (preferably in the upper arm).

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

5. What should I know after being given VAXNEUVANCE?

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 VAXNEUVANCE.
Driving or using machines	<ul style="list-style-type: none">• VAXNEUVANCE is not likely to affect your 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 VAXNEUVANCE. 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 VAXNEUVANCE?](#) 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, muscle aches, headache and joint pain. These side effects are generally mild and last a short time.

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.

VAXNEUVANCE®

Pneumococcal 15-valent Conjugate Vaccine [CRM197 Protein], adsorbed

Consumer Medicine Information (CMI)

This leaflet provides important information about getting VAXNEUVANCE. **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 VAXNEUVANCE.**

Where to find information in this leaflet:

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

1. Why am I being given VAXNEUVANCE?

VAXNEUVANCE is a vaccine given to help protect you against pneumococcal disease caused by 15 types of bacteria called *Streptococcus pneumoniae* or pneumococcus. VAXNEUVANCE can be administered to people 18 years of age and older.

Pneumococcal disease refers to any illness caused by pneumococcus. These bacteria can cause many types of illnesses including lung infection (pneumonia), inflammation of the coverings of the brain and spinal cord (meningitis), and a severe infection in the blood (bacteraemia). These illnesses are more likely to occur in older people and those with certain diseases or behaviors such as cigarette smoking.

VAXNEUVANCE may not protect against diseases caused by types of pneumococcus that are not covered by the vaccine.

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

Warnings

Do not get VAXNEUVANCE if:

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

Check with your doctor if you:

- Have or have had any other medical conditions or any allergies.
- Have a weak immune system (which means your body is less able to fight off infections) or if you are taking certain medicines that may make your immune system weak (for example, immunosuppressants or steroids).

As with other vaccines, VAXNEUVANCE may not fully protect all those who get it.

You may obtain further information from your doctor, nurse or pharmacist, who has more detailed information.

After being given VAXNEUVANCE, 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. They will tell you if you should receive VAXNEUVANCE.

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

Children

It has not yet been established whether VAXNEUVANCE can be given to children and adolescents younger than 18 years of age.

3. What if I am taking other medicines?

VAXNEUVANCE 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 (for example, immunosuppressants or steroids which may make your immune system weak), 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 VAXNEUVANCE.

4. How am I given VAXNEUVANCE?

How much will you be given

- A doctor or nurse will give you this vaccine as an injection into the muscle (preferably in your upper arm).
- Other vaccines may be given at the same time, but at a different site.

5. What should I know after being given VAXNEUVANCE?

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 VAXNEUVANCE.

Driving or using machines

VAXNEUVANCE is not likely to affect your ability to drive or use machines.

Looking after your vaccine

It is unlikely that you will be asked to store VAXNEUVANCE. 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 VAXNEUVANCE. 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.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• Pain, swelling or redness where you had the injection• Feeling tired• Muscle aches• Headache• Joint pain <p>These are the most common side effects and are generally mild and last a short time.</p>	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Tell your doctor, nurse or pharmacist if you notice anything else that may be making you 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 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 VAXNEUVANCE contains

Active ingredient (main ingredient)	Bacterial sugars from 15 types of pneumococcus each linked to a protein (CRM197)* as the active ingredient, adsorbed on aluminium (as aluminium phosphate adjuvant^).
Other ingredients	Sodium chloride Histidine Polysorbate 20 Water for injections

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

^The adjuvant is included to help the vaccine work better.

VAXNEUVANCE does not contain any preservatives.

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

What VAXNEUVANCE looks like

VAXNEUVANCE is an opalescent suspension for injection.

VAXNEUVANCE is available as a prefilled syringe (AUST R 350791).

Who distributes VAXNEUVANCE

Merck Sharp & Dohme (Australia) Pty Limited

Level 1, Building A, 26 Talavera Road

Macquarie Park NSW 2113

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RCN: 000014094-AU

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