

# VAXNEUVANCE®

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## 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.

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- ▼ 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 or your child against pneumococcal disease caused by 15 types of bacteria called *Streptococcus pneumoniae* or pneumococcus. VAXNEUVANCE can be given to adults and children 6 weeks 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 or your child 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 or your child 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 or your child 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 VAXNEUVANCE given?**

A doctor or nurse will give you or your child this vaccine as an injection into the muscle (preferably in the upper arm or thigh for children and the upper arm for adults).

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

## 5. What should I know after being given VAXNEUVANCE?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>● Call your doctor straight away if you or your child have symptoms of an allergic reaction, which may include wheezing or trouble breathing, swelling of the face, lips or tongue, hives or rash.</li><li>● Remind any doctor, nurse or pharmacist you visit that you or your child have been given VAXNEUVANCE.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>● VAXNEUVANCE is not likely to affect the ability to drive or use machines.</li></ul>
<b>Looking after your vaccine</b>	<ul style="list-style-type: none"><li>● 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.</li></ul>

	Keep this vaccine in the original pack until it is time to be given.
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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 for infants and toddlers are pain, swelling, redness or a lump where your child had the injection, being more fussy than usual, being more sleepy than usual, eating less than usual, and fever. The most common side effects for children (2 through 17 years of age) are pain, swelling or redness or a lump where your child had the injection, muscle aches, feeling tired, headache and fever. The most common side effects for adults 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 or your child 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](http://www.tga.gov.au/reporting-problems).

## VAXNEUVANCE®

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

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#### 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.**

**This vaccine can be given to adults and children so you may be reading this leaflet for you or for your child.**

#### **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 is VAXNEUVANCE given?](#)
- [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 or your child against pneumococcal disease caused by 15 types of bacteria called *Streptococcus pneumoniae* or pneumococcus. VAXNEUVANCE can be administered to adults and children 6 weeks 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 younger children, older adults and people with certain diseases or behaviors such as cigarette smoking. In children, pneumococcus is also one of the common causes of ear infections.

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 or your child 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 or your child can be given this vaccine.

#### **Check with your doctor if you or your child:**

- Have or have had any other 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 (for example, immunosuppressants or steroids).

If your child is an infant, also tell your healthcare provider if your child was born prematurely (too early).

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 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 or your child are pregnant or intend to become pregnant. They will tell you if you should receive VAXNEUVANCE.

Talk to your doctor if you or your child 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 younger than 6 weeks of age.

### **3. What if I am taking other medicines?**

Your child can be given VAXNEUVANCE at the same time as other routine childhood vaccines.

In adults, VAXNEUVANCE can be given at the same time as flu (inactivated influenza) vaccine.

Tell your doctor, nurse or pharmacist if you or your child are taking, have recently taken or might take any other vaccines or medicines (for example, immunosuppressants or steroids which may make

the 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 or your child are taking and if these affect VAXNEUVANCE.**

## **4. How is VAXNEUVANCE given?**

### **How VAXNEUVANCE is given**

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

### **How many injections will be given**

- Infants may receive up to 3 doses of the vaccine through 6 months of age based on official recommendations. An additional dose is given to toddlers between 11 through 15 months of age. Your healthcare provider will tell you when your child should receive their next dose.
- If your child did not receive all doses according to official recommendations, your healthcare provider may recommend doses to help them catch up.

- Adults need one dose of the vaccine.
- People with certain medical conditions may need more than one dose of VAXNEUVANCE. Talk to your doctor, nurse or pharmacist about how many doses you or your child should receive.

## **5. What should I know after being given VAXNEUVANCE?**

### **Things you should do**

#### **Call your doctor straight away if you or your child:**

- 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 or your child have been given VAXNEUVANCE.

### **Driving or using machines**

VAXNEUVANCE 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 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 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, nurse or pharmacist if you have any further questions about side effects.

### **Less serious side effects**

<b>Less serious side effects</b>	<b>What to do</b>
Infants and Toddlers:	<b>Speak to your doctor if you or your child have any of these less serious</b>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● Pain, swelling, redness or a lump where your child had the injection</li> <li>● Being more fussy than usual</li> <li>● Being more sleepy than usual</li> <li>● Eating less than usual</li> <li>● Fever</li> </ul> <p>Children 2 through 17 years of age</p> <ul style="list-style-type: none"> <li>● Pain, swelling, redness or a lump where your child had the injection</li> <li>● Muscle aches</li> <li>● Feeling tired</li> <li>● Headache</li> <li>● Fever</li> </ul> <p>Adults 18 years of age and older</p> <ul style="list-style-type: none"> <li>● Pain, swelling or redness where you had the injection</li> <li>● Feeling tired</li> <li>● Muscle aches</li> <li>● Headache</li> </ul>	<p><b>side effects and they worry you.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• Joint pain</li> </ul> <p>These are the most common side effects and are generally mild and last a short time.</p>	

## **Serious side effects**

**Tell your doctor, nurse 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](http://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

<b>Active ingredient (main ingredient)</b>	Bacterial sugars from 15 types of pneumococcus each linked to a protein (CRM197)* as the active ingredient, adsorbed on aluminium (as aluminium phosphate adjuvant^).
<b>Other ingredients</b>	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 or your child 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).

The tip cap and plunger stopper of the pre-filled syringe are not made with natural rubber latex.

## **Who distributes VAXNEUVANCE**

Merck Sharp & Dohme (Australia) Pty Limited

Level 1, Building A, 26 Talavera Road

Macquarie Park NSW 2113

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