

<b>APPROVED PATIENT INFORMATION LEAFLET</b>	<b>Module 1.3.2</b>
<b>VAXNEUVANCE Suspension for Injection</b>	<b>Application no.: 560535</b>
<b>Applicant: MSD (Pty) Ltd</b>	<b>eCTD Sequence: 0004</b>
<b>Date of SAHPRA approved: 13 September 2024</b>	<b>Date approval received: 17 Sep 2024</b>

## SCHEDULING STATUS

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### **VAXNEUVANCE™** Suspension for Injection

**Active ingredient:** Pneumococcal 15-valent Conjugate Vaccine [CRM<sub>197</sub> Protein], adsorbed

**Read all of this leaflet carefully, before you are given VAXNEUVANCE™.**

- Keep this leaflet. You may need to read it again.
- Do not share VAXNEUVANCE™ with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

### **What is in this leaflet**

1. What VAXNEUVANCE™ is and what it is used for
2. What you need to know before you are given VAXNEUVANCE™
3. How to take VAXNEUVANCE™
4. Possible side effects
5. How to store VAXNEUVANCE™
6. Contents of the pack and other information

#### **1. What VAXNEUVANCE™ is and what it is used for**

Your healthcare provider has recommended or given VAXNEUVANCE™ to help protect you or your child against pneumococcal disease caused by 15 types of bacteria called *Streptococcus pneumoniae* or pneumococcus.

The vaccine can be administered to children 6 weeks through 17 years of age and adults 18 years of age and older.

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.

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## 2. What you need to know before you are given VAXNEUVANCE™

You should not be given VAXNEUVANCE™ if you or your child:

- are allergic to any of the ingredients in VAXNEUVANCE™ or to any vaccine containing diphtheria toxoid.

### Warnings and precautions

Before and while you are given VAXNEUVANCE™, tell your health care provider if you or your child:

- about any medical conditions you have or have had, and about any allergies.
- if your immune system is weak (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).

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 the vaccine.

### Children

It has not yet been established whether VAXNEUVANCE™ can be used in children younger than 6 weeks of age.

### Other medicines and VAXNEUVANCE™

Always tell your health care provider if you or your child are taking other medicines. (This includes complementary or traditional 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 health care provider if you or your child are taking, have recently taken or might take any other vaccines or any medicines (for example, immunosuppressants or steroids which may make your immune system weak), including those you can buy over the counter.

### Pregnancy and Breastfeeding

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If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider. They will tell you if you should receive VAXNEUVANCE™.

### **Driving and using machinery**

VAXNEUVANCE™ has no or negligible influence on the ability to drive and use machines.

### **VAXNEUVANCE™ contains sodium.**

This medicine contains less than 1 mmol sodium (23 milligrams) per dose, that is to say essentially 'sodium-free'.

### **3. How is VAXNEUVANCE™ given**

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself VAXNEUVANCE.

Your doctor or other health care professional will administer VAXNEUVANCE injection.

### **Instructions for use**

This vaccine is given as an injection into the muscle (preferably in the upper arm or thigh for children and the upper arm for adults).

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.

### **If you take more VAXNEUVANCE™ than you should**

Since a health care provider will administer VAXNEUVANCE™, he/she will control the dosage.

However, in the event of overdosage your doctor will manage the overdosage.

### **4. Possible side effects**

Like all medicines, VAXNEUVANCE™ can cause side effects, although not everybody gets them.

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The most common side effects seen with VAXNEUVANCE in infants and toddlers are:

- Pain, swelling, redness or a lump where your child got the shot
- Being more fussy than usual
- Being more sleepy than usual
- Eating less than usual
- Fever

The most common side effects seen with VAXNEUVANCE in children 2 through 17 years of age are:

- Pain, swelling, redness or a lump where your child got the shot
- Muscle aches
- Feeling tired
- Headache
- Fever

Frequent side effects seen with VAXNEUVANCE™ in adults 18 years of age and older are:

- Pain, swelling or redness where you got the shot
- Feeling tired
- Muscle aches
- Headache
- Joint pain

These side effects are generally mild and last a short time.

Tell your healthcare provider about these side effects or any other unusual symptoms that develop after you or your child receive this vaccine.

Get medical care right away if you have symptoms of an allergic reaction, which may include:

- Wheezing or trouble breathing
- Swelling of the face, lips or tongue
- Hives
- Rash

There may be side effects that are not listed here. Ask your healthcare provider for more information.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist

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### Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of VAXNEUVANCE™.

### How to store VAXNEUVANCE™

Store refrigerated at 2 °C to 8 °C.

Do not freeze. Protect from light.

Store all medicines out of the reach of children.

Do not use after the expiry date stated on the label.

### 6. Contents of the pack and other information

VAXNEUVANCE™ is available as packs of 1 or 10.

VAXNEUVANCE™ contains bacterial sugars from 15 types of pneumococcus each linked to a protein (CRM<sub>197</sub>) as the active ingredient. The sugars from these bacteria and the protein are not alive and do not cause disease.

In addition, VAXNEUVANCE™ contains the following inactive ingredients: sodium chloride, L-histidine, polysorbate 20, water and aluminum (as aluminum phosphate adjuvant). The adjuvant is included to help the vaccine work better.

VAXNEUVANCE™ does not contain any preservatives.

### What VAXNEUVANCE™ looks like and the contents of the pack

The vaccine is an opalescent suspension.

VAXNEUVANCE™ is a suspension for injection available in 0.5 mL single-dose pre-filled syringes.

### Holder of Certificate of Registration

MSD (Pty) Ltd

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South Africa

Telephone no. 011 655 3000

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