Applicant: MSD (Pty) Ltd
APPROVED PATIENT INFORMATION LEAFLET
VAXNEUVANCE (Pneumococcal 15-valent Conjugate Vaccine [CRM197 Protein], adsorbed)

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

VAXNEUVANCE™ Suspension for Injection

Active ingredient: Pneumococcal 15-valent Conjugate Vaccine [CRM_{197} 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 healthcare 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 is VAXNEUVANCE given
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.

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 healthcare 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 healthcare 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 healthcare 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

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 healthcare 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 < 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 healthcare 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 healthcare 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.

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.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of VAXNEUVANCE.

5. How to store VAXNEUVANCE

Store refrigerated at 2 °C to 8 °C.

Do not freeze. Protect from light.

Shake vigorously before use.

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_{197}) 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 aluminium (as aluminium 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

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