

PRODUCT MONOGRAPH
INCLUDING PATIENT MEDICATION INFORMATION

VAXNEUVANCE®

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

Suspension for intramuscular injection

32 mcg of total pneumococcal polysaccharide conjugated to approximately 30 mcg of CRM₁₉₇ carrier protein per 0.5 mL single-dose

Active immunizing agent

ATC code: J07AL02

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PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

VAXNEUVANCE®

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

Read this carefully before you or your child are given **VAXNEUVANCE®**. This leaflet is a summary and will not tell you everything about this vaccine. Talk to your healthcare professional about your or your child's medical condition and treatment and ask if there is any new information about **VAXNEUVANCE®**.

What is VAXNEUVANCE® used for?

- **VAXNEUVANCE®** is a vaccine for individuals 6 weeks of age and older to help protect against invasive disease caused by 15 types of bacteria called pneumococcus. Invasive disease includes:
 - an infection in the blood.
 - an infection of the lungs (pneumonia) that comes with an infection in the blood.
 - an infection of the coverings of the brain and spinal cord (meningitis).

These illnesses are more likely to occur in younger people, older adults and people with certain diseases or behaviors such as cigarette smoking.

VAXNEUVANCE® will not give you disease caused by pneumococcus.

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

How does VAXNEUVANCE® work?

The vaccine works by helping your body to make its own antibodies which can protect you against pneumococcal disease caused by 15 types of pneumococcus.

What are the ingredients in VAXNEUVANCE®?

Medicinal ingredients: Bacterial sugars from 15 types of pneumococcus each linked to a protein (CRM₁₉₇) as the active ingredient. The sugars from these bacteria and the protein are not alive and do not cause disease.

Non-medicinal ingredients: Aluminum (aluminum phosphate is included to help the vaccine work better), L-histidine, polysorbate 20, sodium chloride and water. **VAXNEUVANCE®** does not contain any preservatives.

VAXNEUVANCE® comes in the following dosage form:

- 0.5 mL prefilled syringes

Do not use VAXNEUVANCE® if:

- You or your child are allergic to any of the ingredients in **VAXNEUVANCE®** or to any vaccine containing diphtheria toxoid.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you or your child get VAXNEUVANCE®. Talk about any health conditions or problems you or your child may have or have had, including:

- any allergies.
- a fever. Your healthcare professional will tell you if you should receive VAXNEUVANCE®.
- a weak immune system (which means your body has a hard time fighting off infections).
- medicines or treatments that might weaken your immune system (like immunosuppressants or steroids).
- have any bleeding problems or bruise easily.

Tell your healthcare provider if you or your child:

- are pregnant or planning to become pregnant. Your healthcare professional will tell you if you should receive VAXNEUVANCE®.
- are breast-feeding or intend to breast-feed. Your healthcare professional will tell you if you should receive VAXNEUVANCE®.

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

Other warnings you should know about:

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

Use of VAXNEUVANCE® with other vaccines and medicines

Tell your healthcare professional 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 vitamins, minerals, natural supplements, alternative medicines or drugs that you or your child can buy over the counter.

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

In children, VAXNEUVANCE® can be given at the same time as other routine childhood vaccines.

How is VAXNEUVANCE® given:

VAXNEUVANCE® is given as a shot into the muscle (preferably in the upper arm for adults and the upper arm or thigh for children).

Usual dose:

Adults:

Adults will receive one dose.

Infants and Children:

Infants may receive 2 or 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.

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

Special Populations

People with certain medical conditions may need more than one dose of VAXNEUVANCE®. Your healthcare provider will tell you how many doses you or your child should receive.

Overdose:

If you think you, or a person you are caring for, have received too much VAXNEUVANCE®, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to go back to the healthcare professional at the scheduled time, ask the healthcare professional for advice.

What are possible side effects from using VAXNEUVANCE®?

As with any vaccine, this vaccine can cause side effects, although not everybody gets them.

The most common 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

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

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

Tell your healthcare professional 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 or your child have symptoms of an allergic reaction, which may include:

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

These are not all the possible side effects you may have when taking VAXNEUVANCE®. There may be side effects that are not listed here. Ask your healthcare professional for more information.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Suspected Side Effects for Vaccines

For the general public: Should you experience a side effect following immunization, please report it to your healthcare professional.

Should you require information related to the management of the side effect, please contact your healthcare professional. The Public Health Agency of Canada, Health Canada and Merck Canada Inc. cannot provide medical advice.

For healthcare professionals: If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (<http://www.phac-aspc.gc.ca/im/ae-fi-essi-form-eng.php>) and send it to your local Health Unit.

Storage:

Store refrigerated at 2°C to 8°C. Do not freeze. Protect from light.

Keep out of reach and sight of children.

If you want more information about VAXNEUVANCE®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the Merck Canada website www.merck.ca, or by calling 1-800-567-2594.

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