Patient Information VAXNEUVANCE™ (pronounced "VAKS-noo-vans") (Pneumococcal 15-valent Conjugate Vaccine)

Before you get VAXNEUVANCE™, read this information sheet and be sure you understand it. If you have questions or experience any side effects, talk to your healthcare provider. This information does not take the place of talking about VAXNEUVANCE with your healthcare provider. Your healthcare provider will decide if VAXNEUVANCE is right for you or your child.

What is VAXNEUVANCE?

- VAXNEUVANCE is a vaccine to help protect against invasive disease caused by 15 types of pneumococcus (pronounced "noo-mo-ca-cus"), a kind of bacteria. Invasive disease includes:
 - an infection in the blood (bacteremia).
 - an infection of the coverings of the brain and spinal cord (meningitis).
- VAXNEUVANCE is for individuals 6 weeks of age and older.
- VAXNEUVANCE will not give you or your child disease caused by pneumococcus.
- VAXNEUVANCE might not protect everyone who gets the vaccine.

Who should not get VAXNEUVANCE?

Do not get VAXNEUVANCE if you or your child:

• have or had an allergic reaction to any of the ingredients in VAXNEUVANCE or to diphtheria toxoid. (See the list of ingredients at the end of this information sheet.)

What should I tell my healthcare provider before getting VAXNEUVANCE?

Tell your healthcare provider if you or your child:

- have or had an allergic reaction to any vaccine.
- have a weak immune system (which means the body has a hard time fighting off infections).
- take medicines or treatments that might weaken the immune system (like immunosuppressants or steroids).
- are pregnant or planning to get pregnant.
- are breast-feeding.

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

How is VAXNEUVANCE given?

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

Children need 4 doses of the vaccine:

- The first injection is given at 2 months old.
- The second injection is given at 4 months old.
- The third injection is given at 6 months old.
- The fourth injection is given at 12 through 15 months old.

If your child did not receive the complete series according to this schedule, your healthcare provider may suggest a catch-up schedule.

Your child may get VAXNEUVANCE at the same time they get other vaccines.

Adults need one dose of the vaccine.

What are the possible side effects of VAXNEUVANCE?

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

- Fever
- Pain, redness, swelling, or a lump where your child got the injection
- More fussy than usual
- More sleepy than usual
- · Eating less than usual

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

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

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 injection
- Feeling tired
- Muscle aches
- Headache
- Joint pain

In most people these side effects went away within three days.

If you or your child have any side effects that become bothersome or any other unusual symptoms that develop after getting this injection, tell your healthcare provider. Tell your healthcare provider right away if you or your child have symptoms of an allergic reaction which may include:

- Difficulty breathing
- Swelling of your face, lips, tongue or throat
- Hives
- Rash

There may be side effects that are not listed here. For more information, ask your healthcare provider.

You may also report any side effects to Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., at 1-877-888-4231 or directly to Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to www.vaers.hhs.gov.

What are the ingredients in VAXNEUVANCE?

Active ingredient: Bacterial sugars from 15 types of pneumococcus each linked to a

protein (CRM₁₉₇). The sugars from these bacteria and the protein

are not alive and do not cause disease.

Inactive ingredients: Sodium chloride, L-histidine, polysorbate 20 and aluminum

(aluminum phosphate is included to help the vaccine work better).

VAXNEUVANCE does not have any preservatives.

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

What if I have other questions?

If you have questions about VAXNEUVANCE, talk to your healthcare provider or call the Merck National Service Center at 1-800-622-4477.



For patent information: www.merck.com/product/patent/home.html

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This Patient Information has been approved by the U.S. Food and Drug Administration.

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