Patient Information

CAPVAXIVE™ (pronounced "Cap-VACKS-iv") (Pneumococcal 21-valent Conjugate Vaccine)

Before you get CAPVAXIVE, 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 CAPVAXIVE with your healthcare provider. Your healthcare provider will decide if CAPVAXIVE is right for you.

What is CAPVAXIVE?

- CAPVAXIVE is a vaccine for individuals 18 years of age and older to help protect against invasive pneumococcal disease and pneumonia caused by certain types of bacteria called pneumococcus.
- These bacteria can cause many types of illnesses, which can be severe, such as infections in:
 - your lungs (pneumonia)
 - the area around your brain and spinal cord (meningitis)
 - your blood (bacteremia)
- You cannot get pneumococcal disease from CAPVAXIVE.
- CAPVAXIVE might not protect everyone who gets the vaccine.

Who should not get CAPVAXIVE?

Do not get CAPVAXIVE if you had an allergic reaction to any of its ingredients, including diphtheria toxoid. (See the list of ingredients at the end of this information sheet.)

What should I tell my healthcare provider before getting CAPVAXIVE? Tell your healthcare provider if you:

- have had an allergic reaction to any vaccine.
- are taking any medications or treatments that might weaken the immune system (like immunosuppressants or steroids).
- have a weak immune system (which means your body is less able to fight off infections).
- are pregnant or planning to become pregnant.
- are breastfeeding or plan to breastfeed.

How is CAPVAXIVE given?

- You will get an injection into the muscle (usually in your upper arm).
- You will get one dose of the vaccine.

What are the possible side effects of CAPVAXIVE?

The most common side effects of CAPVAXIVE are:

- Pain, redness, or swelling where you got the injection
- Feeling tired
- Headache
- Muscle aches
- Fever

These side effects usually last less than 3 days.

Tell your healthcare provider about these side effects or any unusual symptoms that develop after you get 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 not listed here. Ask your healthcare provider for more information.

You may also report any side effects to Merck Sharp & Dohme LLC 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.

Where can I get more information about CAPVAXIVE?

You can ask your pharmacist or healthcare provider for more information about CAPVAXIVE.

What are the ingredients in CAPVAXIVE?

Active ingredient(s): Bacterial sugars from 21 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 ingredient(s): L-histidine, polysorbate 20, sodium chloride, water.

CAPVAXIVE does not have any preservatives.

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

Manufactured by: Merck Sharp & Dohme LLC, Rahway, NJ 07065, USA

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

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