

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

CAPVAXIVE®

Pneumococcal 21-valent conjugate vaccine

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

What is CAPVAXIVE® used for?

- **CAPVAXIVE®** is a vaccine for adults 18 years of age and older to help protect against invasive (severe) pneumococcal disease caused by bacteria called pneumococcus. These bacteria can cause many types of illnesses, which can be invasive (severe), such as infections in:
 - your lungs (called bacteremic pneumonia)
 - the area around the brain and spinal cord (called meningitis).
 - your blood (called bacteremia).

These illnesses are more likely to happen in people who are older or have health conditions (such as alcoholism, asthma, diabetes; heart problems, HIV (human immunodeficiency virus) infection, liver problems, lung problems, kidney problems, or smoking).

How does CAPVAXIVE® work?

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

What are the ingredients in CAPVAXIVE®?

Medicinal ingredients: bacterial sugars from 21 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: L-histidine, polysorbate 20, sodium chloride, water. CAPVAXIVE® does not have any preservatives.

CAPVAXIVE® comes in the following dosage forms:

- 0.5 mL prefilled syringes

Do not use CAPVAXIVE® if:

- You are allergic to any of the ingredients in CAPVAXIVE® including diphtheria toxoid.

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

- any allergies
- a weak immune system (which means your body is less able to fight off infections)
- medicines or treatments that might make your immune system weak
- have any bleeding problems or bruise easily.

Tell your healthcare professional if you:

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

Other warnings you should know about:

As with other vaccines, CAPVAXIVE® may not fully protect all those who get the vaccine. CAPVAXIVE® has not been studied in children who are under 18 years of age.

Use of CAPVAXIVE® with other vaccines and medicines

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

CAPVAXIVE® can be given at the same time as flu (inactivated influenza) vaccine.

How is CAPVAXIVE® given:

- CAPVAXIVE® is given as an injection into the muscle.

Usual dose:

Adults need one dose of the vaccine.

Overdose:

Overdose with CAPVAXIVE® is unlikely as it is supplied as a single dose pre-filled syringe.

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

Missed Dose:

CAPVAXIVE® is a single dose vaccine.

What are possible side effects from using CAPVAXIVE®?

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

The following side effects seen with CAPVAXIVE® include:

Common: may occur in more than 1 in 10 individuals

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

Less common: may occur in more than 1 in 100 and up to 1 in 10 individuals

- Fever

Uncommon: may occur in more than 1 in 1000 and up to 1 in 100 individuals

- Diarrhea, nausea
- Itching at the injection site
- Swollen glands in the neck, armpit, or groin
- Chills
- Dizziness

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

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

These are not all the possible side effects you may have when getting CAPVAXIVE®. There may be side effects 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 CAPVAXIVE®:

- 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 manufacturer's website www.merck.ca, or by calling 1-800-567-2594.

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