## Patient Medication Information

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

# CAPVAXIVE®

### Pneumococcal 21-valent Conjugate Vaccine

This patient medication information is written for the person who will be taking **CAPVAXIVE®**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This patient medication information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **CAPVAXIVE®**, talk to a healthcare professional.

**What CAPVAXIVE® is used for:**

- **CAPVAXIVE®** is a vaccine for adults 18 years of age and older, as well as for children and adolescents 2 to less than 18 years of age who are at increased risk for pneumococcal disease and who have previously completed a primary pneumococcal vaccination regimen. CAPVAXIVE® helps 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 CAPVAXIVE® works:**

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

**The ingredients in CAPVAXIVE® are:**

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 or your child 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 or your child are given CAPVAXIVE®. Talk about any health conditions or problems you or your child 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 or your child:

- 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 2 years of age.

Use of CAPVAXIVE® with other vaccines and medicines

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

CAPVAXIVE® can be given to adults 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 and children 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, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

**Missed Dose:**
CAPVAXIVE® is a single dose vaccine.

**Possible side effects from using CAPVAXIVE®?**
As with any vaccine, this vaccine can cause side effects, although not everybody gets them.

These are not all the possible side effects you may have when given CAPVAXIVE®. If you experience any side effects not listed here, tell your healthcare professional.

The following side effects seen with CAPVAXIVE® in individuals 2 years of age an older 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

Additional side effects of CAPVAXIVE® in children and adolescents are:

Common: may occur in more than 1 in 10 individuals

- Feeling of illness, discomfort, or unease
- Being more fussy than usual

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

- Being more sleepy than usual
- Joint pain

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 or your child get 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 or your child may have when getting CAPVAXIVE®. There may be side effects not listed here. Ask your healthcare professional for more information.

If you or your child 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 or your child 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 (PHAC), Health Canada (HC) 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 (https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization/form.html) 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 the Patient Medication Information by visiting the Health Canada Drug Product Database 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.

This leaflet was prepared by Merck Canada Inc.

Date of Authorization: 2026-09-29

CAPVAXIVE® is a registered trademark of Merck Sharp & Dohme B.V. Used under license.
® Merck Sharp & Dohme LLC. Used under license.
* All other trademarks are the property of their respective owner.

© 2024, 2026 Merck & Co., Inc., Rahway, NJ, USA and its affiliates. All rights reserved.