PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS REGULATIONS (PREPARATIONS) 1986

This medicine is marketed upon physician's prescription only

CAPVAXIVE®

Solution for injection

Each dose (0.5 ml) contains:
Polysaccharides from pneumococcus types 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, de-O-acetylated type 15B, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F and 35B;
Each polysaccharide is linked to a carrier protein (CRM_{197}).
One dose (0.5 mL) contains 4 micrograms of each pneumococcus type and approximately 65 micrograms carrier protein.

For the list of the inactive ingredients and allergens see section 6 "FURTHER INFORMATION". See also section 2.7 "Important information about some of the ingredients of the medicine".

Read the entire leaflet carefully before using the medicine.

- This leaflet contains concise information about the medicine. If you have any further questions, refer to the doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. WHAT CAPVAXIVE IS INTENDED FOR?

CAPVAXIVE is indicated for active immunisation for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* in adults 18 years of age and older.

Therapeutic group: pneumococcal vaccine.

The vaccine works by helping your body to make its own antibodies, which protect you against pneumococcal diseases that include: lung infection (pneumonia), inflammation of the brain and spinal cord (meningitis) and infection in the blood (bacteraemia).

2. BEFORE USING CAPVAXIVE

2.1 Do not use CAPVAXIVE if:

- you are sensitive (allergic) to the active substances, including diphtheria toxoid, or to any of the other ingredients that this medicine contains (for a list of inactive ingredients, see section 6 "FURTHER INFORMATION").

2.2 Special warnings regarding use of CAPVAXIVE

Before vaccination with CAPVAXIVE tell your doctor if:

- you have a high fever or severe infection. In these cases, the vaccination may have to be postponed until you have recovered. However, a mild fever or infection (for example having a cold) itself is not a reason to delay vaccination.
- you have any bleeding problems, bruise easily, or are taking medicines to prevent blood clots.
- you have anxiety related to injections or have ever fainted after any injection.
- your immune system is weakened (which means your body is less able to fight off infections) or if you are taking certain medicines that may weaken your immune system.

As with any vaccine, CAPVAXIVE may not fully protect all those who get the vaccine.

2.3 Children and adolescents

There are no data on the efficacy and safety of CAPVAXIVE in children and adolescents younger than 18 years of age.
CAPVAXIVE is not indicated for children and adolescents below 18 years of age.

2.4 Interactions with other medicines/vaccines
CAPVAXIVE can be given at the same time as the flu vaccine (inactivated influenza).

If you are taking, have recently taken, or might take other medicines including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Also tell your doctor or pharmacist if you have recently received or plan to receive any other vaccine.

Before vaccination with CAPVAXIVE tell your doctor if:
- you are taking medicines to prevent blood clots.
- you are taking certain medicines that may weaken your immune system.

See also section 2.2 "Special warnings regarding use of CAPVAXIVE".

2.5 Pregnancy and breast-feeding
There are no data on administration of the vaccine in pregnant women, and it is not known whether the vaccine is excreted into breast milk.
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist before you receive this vaccine.

2.6 Driving and using machines
CAPVAXIVE has no or negligible influence on the ability to drive and use machines. However, some of the effects mentioned under section 4 "SIDE EFFECTS" may temporarily affect the ability to drive or use machines.

2.7 Important information about some of the ingredients of the medicine
CAPVAXIVE contains sodium
This medicine contains less than 1 mmol sodium (23 milligrams) per dose, that is to say essentially 'sodium-free'.

CAPVAXIVE contains polysorbate 20
This medicine contains 0.5 mg of polysorbate 20 in each 0.5 mL dose of solution for injection.
Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

3. HOW IS CAPVAXIVE GIVEN?

Always use CAPVAXIVE according to the doctor's instructions.
You should check with the doctor or pharmacist if you are not sure regarding the dosage and treatment regimen.
The dosage and treatment regimen will be determined by the doctor only.

Tell your doctor, pharmacist, or nurse if you have been given a pneumococcal vaccine before.

Dosage
Adults

You will receive one injection (1 dose of 0.5 mL).
Your doctor or nurse will give the vaccine into your upper arm muscle.

Do not exceed the recommended dose.

If you have accidentally received a higher dose than you should

If you have received an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or to a hospital emergency room and bring the package of the medicine with you.

Follow the instructions as recommended by the doctor.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take a medicine. Wear glasses if you need them.

If you have further questions regarding the use of the medicine, consult with a doctor or a pharmacist.

4. SIDE EFFECTS

Like all vaccines, CAPVAXIVE may cause side effects, in some users.
Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

Serious side effects
Rare side effects (may affect up to 1 in 1000 people):
CAPVAXIVE may cause allergic (hypersensitivity) reactions including excessive contraction of the airway muscles causing breathing difficulty (bronchospasm). 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

Additional side effects
The following side effects have been seen after the use of CAPVAXIVE:

Very common side effects (may affect more than 1 in 10 people):

- Headaches
- Pain at the injection site
- Feeling tired

Common side effects (may affect up to 1 in 10 people):

- Muscle aches (very common in people 18 to 49 years of age)
- Redness or swelling at the injection site (very common in people 18 to 49 years of age)
- Fever

Uncommon side effects (may affect up to 1 in 100 people):

- Swelling of lymph nodes
- Dizziness
- Feeling sick (nausea)
- Diarrhoea
- Vomiting
- Joint pain
- Itching at injection site
- Chills
- Bruising at injection site

These side effects are generally mild to moderate in intensity and last a short time.

If a side effect appears, if any of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by using the link "Adverse Drug Reactions Report" at the home page of the Ministry of Health's web site (www.health.gov.il) which refers to the online side effects reporting form, or by using the link:
https://sideeffects.health.gov.il

5. HOW TO STORE CAPVAXIVE?

- Avoid Poisoning! This vaccine and any other medicine must be stored in a safe place out of the reach and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of the indicated month.
- **Storage conditions:**
  Store in a refrigerator (2° C – 8° C). Do not freeze. Keep the pre-filled syringe in the outer carton in order to protect from light. CAPVAXIVE should be administered as soon as possible after being removed from the refrigerator. However, in circumstances where CAPVAXIVE is temporarily held outside of refrigeration, the vaccine is stable at temperatures up to 25° C for 96 hours. At the end of this time period CAPVAXIVE should be used or discarded. This information is intended to guide healthcare professionals in case of temporary temperature excursions only.
- Medicines should not be disposed of via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredients, CAPVAXIVE also contains:

Sodium chloride (NaCl), L-histidine, polysorbate 20 (E432), hydrochloric acid (HCl; for pH adjustment) and water for injections.
For more information on polysorbate 20 (E432), see section 2.7 “Important information about some of the ingredients of the medicine”.

What CAPVAXIVE looks like and contents of the pack
CAPVAXIVE is a colourless, clear to opalescent solution for injection (injection), provided in a single-dose, pre-filled syringe (0.5 mL).

Pack sizes:
CAPVAXIVE is available in pack sizes of 1 or 10 pre-filled syringes, either without needles, with 1 separate needle or with 2 separate needles per pre-filled syringe.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Importer:
Merck Sharp & Dohme (Israel-1996) Company Ltd., 34 Ha’charash St., Hod-Hasharon.

Approved in January 2026.

Drug registration no. listed in the official Registry of the Ministry of Health:
180-62-38434

The following information is intended for healthcare professionals only:

- The vaccine should be used as supplied.
- Inspect the solution visually for particulate matter and discolouration prior to administration. Discard the vaccine if particulates are present and/or if it appears discoloured.
- Attach a needle with Luer lock connection by twisting in a clockwise direction until the needle fits securely on the syringe.
- CAPVAXIVE should be administered by intramuscular injection only. This vaccine should be administered preferably in the deltoid muscle of the upper arm in adults, with care to avoid injection into or near nerves and blood vessels.

CAPVAXIVE can be administered concomitantly with quadrivalent influenza vaccine (split virion, inactivated) in adults. Different injectable vaccines should always be administered at different injection sites.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.