

## Package leaflet: Information for the user

### **CAPVAXIVE® solution for injection in pre-filled syringe** Pneumococcal polysaccharide conjugate vaccine (21-valent)

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

#### **Read all of this leaflet carefully before you are vaccinated because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This vaccine has been prescribed for you only. Do not pass it on to others.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What CAPVAXIVE is and what it is used for
2. What you need to know before you receive CAPVAXIVE
3. How CAPVAXIVE is given
4. Possible side effects
5. How to store CAPVAXIVE
6. Contents of the pack and other information

#### **1. What CAPVAXIVE is and what it is used for**

CAPVAXIVE is a pneumococcal vaccine given to:

- **people aged 18 years and older** to help protect against illnesses caused by a bacterium called *Streptococcus pneumoniae* or pneumococcus. These diseases include: lung infection (pneumonia), inflammation of the brain and spinal cord (meningitis) and infection in the blood (bacteraemia).

The vaccine works by helping your body to make its own antibodies, which protect you against these diseases.

#### **2. What you need to know before you receive CAPVAXIVE**

##### **Do not receive CAPVAXIVE:**

- if you are allergic to the active substances, including diphtheria toxoid, or to any of the ingredients of this vaccine (listed in section 6).

##### **Warnings and precautions**

Talk to your doctor, pharmacist, or nurse before you receive CAPVAXIVE 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.

**Children and adolescents**

CAPVAXIVE has not been studied in children and adolescents younger than 18 years of age.

**Other medicines/vaccines and CAPVAXIVE**

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

Tell your doctor, pharmacist, or nurse if:

- you are taking, have recently taken, or might take any other medicines.
- you have recently received or plan to receive any other vaccine.

**Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist, or nurse for advice before you receive this vaccine.

**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 “Possible side effects” may temporarily affect the ability to drive or use machines.

**CAPVAXIVE contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) 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 CAPVAXIVE is given**

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

**Adults**

You will receive 1 injection (1 dose of 0.5 mL).

Your doctor or nurse will give the vaccine into your upper arm muscle.

If you have any further questions on the use of CAPVAXIVE, ask your doctor, pharmacist, or nurse.

**4. Possible side effects**

Like all vaccines, CAPVAXIVE can cause side effects, although not everybody gets them.

**Serious side effects**

**Rare** (may affect up to 1 in 1 000 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

### **Other side effects**

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

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

- Headaches
- Pain at the injection site
- Feeling tired

**Common** (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** (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 or moderate and last a short time.

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

## **5. How to store CAPVAXIVE**

Keep this vaccine out of the sight and reach of children.

Do not use this vaccine after the expiry date which is stated on the carton and syringe label after EXP. The expiry date refers to the last day of that month.

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.

## **6. Contents of the pack and other information**

### **What CAPVAXIVE contains**

The active substances are:

- 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 (4 micrograms of each type);

Each polysaccharide is linked to a carrier protein (CRM<sub>197</sub>). The polysaccharides and the carrier protein are not alive and do not cause disease.

One dose (0.5 mL) contains approximately 65 micrograms carrier protein.

The other ingredients are sodium chloride (NaCl), histidine, polysorbate 20 (E432), hydrochloric acid (HCl; for pH adjustment) and water for injections. For more information on polysorbate 20 (E432), see Section 2.

### **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). 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 Manufacturer**

#### **Marketing Authorisation Holder:**

Merck Sharp & Dohme (UK) Limited  
120 Moorgate  
London EC2M 6UR  
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#### **Manufacturer:**

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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.

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