

**meningococcal polysaccharide vaccine, groups A and C,
freeze-dried
10 doses**



Vaccinum meningococcale polysaccharidicum

composition

1 dose of vaccine contains:

- <i>N. meningitidis</i> group A polysaccharide	50.0 µg
- <i>N. meningitidis</i> group C polysaccharide	50.0 µg
- lactose	5.0 mg
- sodium chloride	4.5 mg
- sterile water for injections	0.5 ml

pharmaceutical form and packaging

Meningococcal polysaccharide vaccine, groups A and C is a freeze-dried preparation for subcutaneous injection.

Sterile water for injections to prepare the suspension for injections.

Container/dose

Presentation

- Vial/10 doses:
- Box with 1 vial containing 10 doses of vaccine and 1 ampoule containing 5 ml of sterile water for injections
 - Box with 50 vials containing 10 doses of vaccine and box with 50 ampoules containing 5 ml of sterile water for injections

pharmacotherapeutic group (ATC code)

J07AH Meningococcal vaccine

legal category

Subject to medical prescription, supply through medical institutions only.

pharmacological properties

The vaccine provides active protection against meningococcal disease caused by *N. meningitidis* groups A and C. It contains freeze-dried, purified meningococcal polysaccharides (purity more than 90%), isolated from *N. meningitidis* groups A and C. The vaccine is stabilized with lactose. Sodium chloride is added to ensure isotonicity.

Studies have shown that a protective antibody level is achieved in 90% of immunised persons.

The vaccine meets the requirements of the World Health Organization (WHO) and the European Pharmacopoeia (Ph.Eur.)

special warnings and precautions for use

- a detailed anamnesis should be obtained prior to vaccination;
- the vaccine is recommended to be used in individuals over the age of 10 months;
- immunization in individuals with partial immunodeficiency, either congenital or as a result of immunosuppressive therapy (including radiation, corticosteroids, cytostatics) and in individuals with HIV-infections may result in a lower antibody level.

In the event of an anaphylactic reaction, anti-shock therapy should be applied!

interaction with other medicinal products

When and if the vaccine is used in individuals who are on immunosuppressive therapy, an immune response to the vaccine may not occur.

pregnancy and lactation

There is no evidence that the vaccine has a teratogenic effect, but as a measure of precaution, vaccination should be postponed until the end of pregnancy, except when a physician finds strong indications for it.

dosage and method of administration

The freeze-dried vaccine should be dissolved immediately prior to use!

Ten vaccine doses are dissolved in 5 ml of sterile water for injections.

A sterile needle and syringe are used to transfer the indicated amount of diluent into the vial containing the freeze-dried vaccine. **Shake gently in order to avoid the formation of bubbles.** The vaccine quickly dissolves, forming a slightly opalescent solution.

A new sterile needle and syringe should be used for each individual vaccination. Before vaccination, the vaccine should be warmed up to body temperature (by holding it in the hand)! The dissolved, but unused vaccine should be discarded.

The vaccine dose is 0.5 ml. It is administered by **subcutaneous injection** into the deltoid area. In small children, the vaccine is administered by **subcutaneous injection** into the external side of the thigh.

adverse effects

Local

- induration, soreness and redness may occur at the injection site and persist for 1 or 2 days.

General:

- in rare cases, transient increase of body temperature may occur.

shelf life and storage

Shelf life is indicated on the packaging. Do not use after the expiration date indicated on the label. Store at a temperature of 2 to 8 °C, protected from light. Do not freeze.

date of revision of the text

07/2006

number and date of marketing authorisation number

- box: 1 vial/10 doses; 1 ampoule/5 ml of sterile water for injections UP/I-530-09/05-01/356

- box: 50 vials/10 doses + box: 50 ampoules/5 ml of sterile water for injections UP/I-530-09/05-01/373