

# Ingovax<sup>®</sup> ACWY

Meningococcal Polysaccharide Vaccine BP

## Presentation

Ingovax<sup>®</sup> ACWY: Each vial contains lyophilized preparation of Meningococcal Polysaccharide Vaccine BP containing purified polysaccharides from *Neisseria meningitidis* serogroups A, C, W135 and Y. After reconstitution 0.5 ml contains  $\geq 50$   $\mu$ g of each of the polysaccharide serogroups A, C, W135 and Y.

## Description

Ingovax ACWY is a freeze-dried preparation of the group-specific polysaccharide antigens from *Neisseria meningitidis* Group A, Group C, Group Y and Group W135. When reconstituted, the vaccine is a clear, colorless sterile solution for subcutaneous use.

## Indications and uses

Ingovax ACWY is indicated for the active immunization of children from 2 years of age, adolescents and adults against meningococcal disease caused by meningococci of serogroups A, C, W135 and Y. The vaccine may also be used for:

- Subjects who are living in closed communities and close contacts of patients with disease caused by meningococci of serogroups A, C, W135 and Y.
- Travellers to countries where the disease is epidemic or highly endemic.

## Dosage and administration

The immunizing dose is a single injection of 0.5 ml administered subcutaneously.

### Primary Immunization

For both adults and children from 2 years of age, vaccine is administered subcutaneously as a single 0.5 ml dose. Protective antibody levels may be achieved within 7 to 10 days after vaccination.

### Revaccination

Revaccination of a single 0.5 ml dose administered subcutaneously may be indicated for individuals at high-risk of infection, particularly children who were first vaccinated when they were less than 4 years of age; such children should be considered for revaccination after 2 or 3 years if they remain at high-risk. Although, it has not been confirmed the necessity for the older children and adults to be re-vaccinated, if the antibody level has rapidly declined after the first vaccination, then re-vaccination is considered after primary immunization within 3~5 years.

### Method of administration

Ingovax ACWY is for subcutaneous use only. Do not inject intravenously.

The vaccine should be reconstituted only with the supplied solvent. To reconstitute the vaccine, transfer content of supplied diluents into the vial containing freeze-dried preparation. Do not shake during & after reconstitution. The reconstituted vaccine should be inspected for any foreign particulate matter prior to administration. The reconstituted vaccine should be administered within 30 minutes after reconstitution and the syringe should be destroyed after use.

### Contraindications

Hypersensitivity to the active substances or to any of the excipients.

### Co-administration

Meningococcal polysaccharide vaccine can be administered at the same time with other vaccines. Different injectable vaccines should always be administered at a different injection site with different syringe.

### Precautions

As with other vaccines, the administration of Meningococcal polysaccharide vaccine should be postponed in subjects suffering from acute severe febrile illness. The presence of a minor infection, however, is not a contraindication for immunization.

This vaccine gives no protection against meningococcal meningitis caused by meningococci belonging to serogroups other than A, C, W135 and Y.

If administered to subjects with impaired immune responses, the vaccine may not induce an effective response.

As with all injectable vaccines, appropriate medication (e.g. adrenaline) should always be readily available for treatment in case of anaphylactic reactions following the administration of the vaccine.

Vaccination should be preceded by a review of the medical history (especially with regard to previous vaccination and possible occurrence of undesirable events) and a clinical examination.

### Side effects

Meningococcal polysaccharide vaccine is generally well tolerated. Adverse reactions usually occur within 48 hours following vaccination.

- *Metabolism and nutrition disorders*: Common: appetite lost
- *Psychiatric disorders*: Very common: irritability
- *Nervous system disorders*: Very common: drowsiness, headache. Uncommon: dizziness
- *Gastrointestinal disorders*: Common: gastrointestinal symptoms e.g. nausea, vomiting and diarrhea
- *Musculoskeletal and connective tissue disorders*: Common: myalgia.
- *General disorders and administration site conditions*: Very common: pain and redness at the injection site, fatigue. Common: swelling at the injection site, fever.

### Pregnancy & Lactation

*Pregnancy*: Adequate human data on use during pregnancy and adequate animal reproduction studies are not available. This vaccine should be used during pregnancy only when clearly needed and when the possible advantages outweigh the possible risks for the fetus.

*Lactation*: Adequate data on the administration of this vaccine to women who are breast-feeding are not available. This vaccine should be administered to women who are breast-feeding when needed and the possible advantages outweigh the possible risks.

### Overdose

Not applicable.

### Storage

- Keep out of the reach and sight of children
- Store and transport at +2 °C to + 8 °C
- Do not freeze
- Protect from light
- The vaccine should be used within 30 minutes after reconstitution

### Commercial Pack

Ingovax<sup>®</sup> ACWY: Each box contains 1 vial of lyophilized preparation of Meningococcal Polysaccharide Vaccine BP, 1 ampoule containing 0.5 ml WFI and a sterile disposable syringe.

 Manufactured by  
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