SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICAL PRODUCT

Ingovax ACWY

Powder and solvent for solution for injection in a vial

Meningococcal polysaccharide groups A, C, Y and W135 vaccine

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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 ≥ 50 µg of each of the polysaccharide serogroups A, C, W135 and Y.After reconstitution, 1 dose (0.5 ml) contains:

3. PHARMACEUTICAL FORM

Powder and solvent for solution for injection in a vial.

Powder and solvent for solution for injection. The powder is white.

The solvent is clear and colorless

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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.

4.2 Posology and method of administration

Posology

1 dose of 0.5 ml.

Subjects who remain at increased risk of invasive meningococcal disease may be revaccinated at intervals. Intervals should be in accordance with available official recommendations.

Dosage and administration

Child & Adults

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.

Method of administration

Meningococcal polysaccharide vaccine should be given by deep subcutaneous injection into the anterolateral aspect of upper thigh in toddlers and outer aspect of arm in older children and adults. Do not give intravenously.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients
Hypersensitivity after previous administration of Ingovax ACWY

4.4 Special warnings and precautions for use

- 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.
- Ingovax ACWY should under no circumstances be administered intravascularly or intradermally
- 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.
- The vaccine should not be used if vaccine bottle has cracks or unclear labels, the vaccine is beyond shelf life, and abnormal appearance (such as turbidity) is observed after reconstitution.
- The vaccine should be used immediately after opening.
- Freezing is prohibited.

4.5 Interaction with other medical products and forms of interaction

Use with other vaccines

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.

4.6 Pregnancy and 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.

Breast-feeding

Adequate data on the administration of this vaccine to women who are breast-feeding are not available. This vaccine should only be used during breast-feeding when the possible advantages outweigh the potential risks.

Fertility

No fertility data are available.

4.7 Undesirable 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.

4.9 Overdose

Not applicable

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Bacterial vaccines

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.

Immune response

Although there are no data available concerning the protective efficacy of Ingovax ACWY, immunogenicity is accepted as an indication of protective efficacy.

5.2 Pharmacokinetic properties

Evaluation of pharmacokinetic properties is not required for vaccines.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on general safety studies.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mannitol ..... q.s.

Sucrose ..... q.s.

Sodium Chloride..... q.s.

Tris Base ..... ……q.s.

0.5M Glacial Acetic Acid……q.s.

0.5M Sodium Hydroxide……..qs

Water for Injection…… qs

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

2 years

After reconstitution, the vaccine should be used immediately. However, chemical and physical in-use stability has been demonstrated for 8 hours at 2-8°C.

6.4 Special precautions for storage

- Keep out of the reach and sight of children
- Store and transport at +2 ^{O}C to +8 ^{O}C
- Protect from light
- Discard vaccine if frozen

6.5 Nature and contents of container

Powder in a vial with grey Bromobutyl rubber stoppers and aluminium overcaps fitted with blue flip-off tops.

6.6 Special precautions for disposal and other handling

- The vaccine should be inspected visually for any foreign particulate matter and/or other coloration prior to administration. In the event of either being observed, discard the vaccine.
- The vaccine must be reconstituted by adding the entire content of the supplied container of solvent to the vial containing the powder. The powder should be completely dissolved in the solvent. The reconstituted vaccine is a clear colourless solution.
- Any unused medicinal product or waste material should be disposed of in accordance with local requirements.
- The vaccine should never be administered intravenously.
- Any unused medicinal product or waste material should be disposed of in accordance with local requirements.
- The vaccine should not be used if vaccine bottle has cracks or unclear labels, the vaccine is beyond shelf life, and abnormal appearance (such as turbidity) is observed after reconstitution

7. Marketing authorisation holder

Incepta VaccineLtd.

Bara Rangamatia

Zirabo, Ashulia

Savar, Dhaka

Bangladesh

8. Drug authorisation number(s)

Ingova ACWY 0.5 ml - 363-07-069

9. Date of first authorisation/renewal of the authorization

July 07, 2015

10. DATE OF REVISION OF THE TEXT

October,2021