

**MENINGOCOCCAL POLYSACCHARIDE A & C VACCINE (I.P.)****Bi Meningo™****DESCRIPTION**

Polysaccharide vaccine against cerebrospinal meningitis and other diseases caused by *Neisseria meningitidis* (Group A & C). Bi Meningo™ fulfills the requirements of Meningococcal Polysaccharide Vaccine as given in Indian Pharmacopoeia. The manufacturing facilities meets the requirements of cGMP guidelines of revised schedule 'M' of Government of India and W.H.O. G.M.P. Guidelines. The vaccine also confirms to W.H.O. requirement for biological substances (W.H.O. T.R.S. No. 594 (1976), 658 (1981) (Addendum 1980) and 904 (2002) (Amendment 1999).

INDICATIONS

Prevention of cerebrospinal meningitis caused by *Neisseria meningitidis* (Group A & C). Vaccination is recommended in regions of endemic infection, travelers to countries with epidemic meningococcal disease, household or institutional contacts, military recruits. It is also recommended for subjects living in closed communities and in close contact of patients/carriers of meningococcal Group A & C.

COMPOSITION

Each dose (0.5 ml) of vaccine contains :

- Purified Polysaccharide of *Neisseria meningitidis*
 - Group A.....50 µg
 - Group C.....50 µg
- Lactose I.P. (Stabilizer).....5mg
- Thimerosal I.P. (Preservative).....0.05 mg

PHARMACEUTICAL DOSAGE FORM

Reconstitute the lyophilisate with the entire content of the vaccine diluent provided. Shake gently for full reconstitution. The multi dose vaccine vials after opening can be kept at 2-8°C and used for upto 28 days after opening provided sterile techniques have been used for withdrawing vaccine and expiry date have not passed.

ADDITIONAL INFORMATION ON THE STABILITY

The reconstituted vaccine is stable for 1 month when kept at +2 to +8°C and for 1 week at 25 ± 2°C.

CONTRA-INDICATIONS

- Hypersensitivity to any of the vaccine component.
- Ongoing acute or chronic illness like fever, severe infection, persistent diarrhoea, vomiting.

INSTRUCTION FOR USE

The vaccine should be shaken gently and visually inspected for any foreign particulate matter and/ or variation of physical aspect prior to administration. In the event of either of the above, being observed, discard the vaccine.

As with other vaccines, in rare cases anaphylactic shock may occur in susceptible individual. The mainstay in the treatment of severe anaphylaxis is the prompt use of adrenaline, which can be life saving. It should be used at the first suspicion of anaphylaxis. The vaccinees should remain under observation for not less than 30 minutes for possibility of occurrence of rapid allergic reactions. Hydrocortisone & antihistaminics should also be available in addition to supportive measures such as oxygen inhalation.

DOSAGE AND ADMINISTRATION

- Administer the vaccine (0.5ml) by intramuscular or subcutaneous route. It should under no circumstances be administered intravenously.
- Administration of single 0.5 ml dose of Bi Meningo™ elicits a significant bactericidal antibody response in about 100% of subjects. Immunity is conferred for three years.
- The seroconversion rate of children vaccinated under the age of two years is lower for the serogroup C. However, the seroconversion rate for the serogroup A is acceptable in children from the age of 6 months onwards.

PREGNANCY - BREAST FEEDING

The safety of Meningococcal Polysaccharide Vaccine in pregnant women has not been established. However, it is not categorically contra-indicated during pregnancy or breast - feeding and may be administered where there is a genuine epidemic risk.

SIDE EFFECTS

Reaction to vaccination generally consists of localized injection site reaction (pain, redness), transient hyperthermia, headache, vomiting in children etc.

MEDICATION TO COUNTER POST-VACCINATION SIDE EFFECTS

- Give Benadryl / Avil syrup to children upto 10 years of age about half an hour before vaccination. This will prevent vomiting, headache, shivering symptoms which may happen within two hours of vaccination.
- Paracetamol or Ibuprofen cover for 36 hours after vaccination shall decrease the intensity of side effects.

STORAGE

Store between +2°C to +8°C in the refrigerator.

PACK SIZE

One dose in glass vial with appropriate diluent and disposable syringe.

Manufactured & Marketed by :**Bio-Med**
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AN ISO 9001, 14001
WHO GMP CERTIFIED CO.

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