

Summary of Product Characteristics of Meningococcal Polysaccharide A & C Vaccine I.P.

Brand Name: Bi Meningo™

Manufactured By:

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Summary of Product Characteristics

(As per Annexure C of Module 1 of Guidance for industry by CDSCO)

1. Name of the Medicinal Product :-

Meningococcal Polysaccharide A & C Vaccine I.P.

Brand name: - Bi Meningo™

2. Qualitative and Quantitative 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)	5 mg
Thimerosal I.P. (Preservative)	0.01 %

3. Pharmaceutical Form :-

Lyophilised vaccine with vaccine diluent for reconstitution.

4. Clinical Particulars :-

4.1 Therapeutic 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 and military recruits.

It also recommended for subjects living in closed communities and in close contact of patients/carriers of meningococcal Group A & C.

4.2 Physiology and method of administration:

- Administer the vaccine (0.5 ml) by intramuscular or subcutaneous route in persons 2 years of age and older. It should under no circumstances be administered intravenously.
- Reconstitute the lyophilisate with the entire content of the diluent provided with the vaccine. 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 technique have been used for withdrawing vaccine and expiry date have not passed.
- Administration of single 0.5 ml dose of Bi Meningo™ elicits a significant bactericidal antibody response in about 100% if subjects. Immunity is conferred for three years.

4.3 Contra indications:

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

4.4 Special warnings and precaution for use:

- In case vaccine have not been stored in proper cold chain and/or crack in vial, the integrity of pellet/powder of vaccine could change. Before using the vaccine check the powder/pellet integrity.
- 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 lifesaving. It should be used at the first suspicion of anaphylaxis. The vaccinee should remain under observation for not less than 30 minutes for possibility of occurrence of rapid allergic reactions. Hydrocortisone & antihistaminic should also be available in addition to supportive measures such as oxygen inhalation.

4.5 Interaction with other medicinal products and other forms of interaction :

Not Applicable

4.6 Pregnancy & Lactation:

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.

4.7 Effects on ability to drive and use machines:

Not Applicable

4.8 Undesirable effects :

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

4.9 Over dose:

Not Applicable

5. Pharmacological Properties:-

5.1 Pharmacodynamics Properties:

Not applicable for vaccines as immunizing doses are too less for Pharmacodynamics studies.

5.2 Pharmacokinetic Properties:

Evaluation of Pharmacokinetic properties is not required for vaccine.

5.3 Preclinical Safety Data:

In the Animal Toxicity studies, no abnormal or adverse effects due to Meningococcal Polysaccharide Vaccine (Group A & C) were noted in animals during the acute toxicity studies as well as long term toxicity studies. Meningococcal Polysaccharide Vaccine (Group A & C) has passed the Animal Toxicity studies in animals.

6. Pharmaceutical Particulars:-

6.1 List of excipients :

Each dose (0.5 ml) of vaccine contains:

- Lactose I.P. (Stabilizer).....5 mg
- Thimerosal I.P.(Preservative).....0.01%

6.2 Incompatibilities:

Not applicable

6.3 Shelf life :

Use the product within 24 months from the date of manufacture.

6.4 Special precaution for storage:

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

6.5 Nature & contents of container:

Various material used for the containerization of vaccine are as follows.

- **Glass Vials :**

2 ml clear tubular glass vial (USP type I)

5 ml clear tubular glass vial (USP type I)

- **Rubber closures :**

13 mm Slotted Grey Butyl 'Unister RFU' Sterile Rubber Stopper

- **Aluminium Seals :**

13 mm flip off Green (GN-19) aluminium seal.

Materials used for the containerization of vaccine diluent are as follows:

- **Glass vial :**

5ml clear tubular glass vial (USP type I)

- **Rubber Closures:**

13 mm non slotted Grey butyl, 'Unister RFU' sterile Rubber stopper.

- **Aluminium Seals :**

13 mm flip off white (WE1) aluminium seal.

6.6 Special precautions for disposal:

No special requirements

7. Marketing authorization Holder :-

BIO-MED (P) LTD.

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Website : www.biomed.co.in

8. Marketing authorization number :-

Form 46 Permission No. MF-7/09 dated 12/01/2009.

9. Date of first authorization/Renewal of the authorization:-

a) NOC for Additional item vide F.No. 12-37/Biomed/PAC-Meningococcal/14-BD dated 18/12/2014

b) Additional item license No. vide letter No. Drug/837/378 dated 16/01/2015.

c) Renewal of authorization on Form 26-H dated 21 May 2014.

10. Date of Revision of the text :-

January, 2024