Summary of Product Characteristics of Meningococcal Polysaccharide Vaccine (Group A, C, Y, & W135) I.P.

Brand Name: Quadri 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 (Generic Name) :-

1.1 Meningococcal Polysaccharide Vaccine (Group A, C, Y & W135) I.P.

1.2 Brand Name: Quadri Meningo™

2. Qualitative and Quantitative Composition :-

Each dose (0.5 ml) of vaccine contains:-

- Purified Polysaccharide of *Neisseria Meningitidis*
  Group A.....50µg
  Group C.....50µg
  Group Y.....50µg
  Group W135.....50µg
- Lactose IP (Stabilizer).....5 mg
- Thimerosal IP (preservative).....0.05mg

3. Pharmaceutical Form(Dosage Form and Strength) :-

Reconstitute the lyophilisate with the entire content of the diluents provided with the vaccine (Sodium Chloride Injection, 0.9% w/v sodium chloride). 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 been passed.

4. Clinical Particulars :-

4.1 Therapeutic Indications:

For the prevention of cerebrospinal meningitis caused by Neisseria meningitides Group A, C, Y, W135.Vaccination is recommended for travelers moving in the endemic regions. Prevention of cerebrospinal meningitis caused by *Neisseria Meningitidis* Group A, C, Y & W135. Vaccination is recommended in regions of endemic infection, travelers to countries with epidemic meningococcal disease (Hajj Pilgrims) 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, Y & W135.

4.2 Posology and method of administration:

- Administer the vaccine (0.5 ml) by intramuscular or subcutaneous route. It should under no circumstances be administered intravenously.

- Administration of single 0.5 ml dose of Meningococcal Polysaccharide Vaccine elicits a significant bactericidal antibody response in about 100% of subjects 2 years and above. Immunity is conferred for three years.
- The seroconversion rate of children vaccinated under the age of two years is lower for the seroGroup C and to lesser extent for the seroGroups W135 and Y. However, the seroconversion rate for the seroGroup A is acceptable in children from the age of 6 months onwards.

4.3 Contraindications:

- 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 vaccines 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 for powder/ pellet integrity.

The vaccine after reconstitution should be shaken gently and visually inspected for any foreign particulate matter. 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 & antihistaminics should also be available in addition to supportive measures such as oxygen inhalation.

Precaution for use :

- Medical practioners/Healthcare professional can provide Diphenhydramine hydrochloride/ pheniramine maleate 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.

4.5 Interaction with other medicinal products and other forms of interaction (Drug Interactions) :

Not Applicable

4.6 Use in special populations (such as pregnant women, lactating women, pediatric patients, geriatric patients etc.) (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 consist 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 Mechanism of action :

Helps to develop immunity by initiating a mild infection, this type of infection does not cause illness but stimulates the production of antibodies to protect against infections.

5.2 Pharmacodynamics Properties:

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

5.3 Pharmacokinetic Properties:

Evaluation of Pharmacokinetic properties is not required for vaccine.

6. Preclinical Safety Data(Non-Clinical Properties):-

6.1 Animal Toxicology or Pharmacology :

In the Animal Toxicity studies, no abnormal or adverse effects due to Meningococcal Polysaccharide Vaccine (Group A, C, Y & W135) were noted in animals during the acute toxicity studies as well as long term toxicity studies. Meningococcal Polysaccharide Vaccine (Group A, C, Y & W135) has passed the Animal Toxicity studies in animals.

7. Description:-

Polysaccharide vaccine against cerebrospinal meningitis caused by Neisseria meningitides Group A, C, Y & W135. Quadri Meningo™ fulfils 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 the Drugs & Cosmetic Act, Government of India.

8. Pharmaceutical Particulars:-

8.1 List of excipients :

Each dose (0.5 ml) of vaccine contains:

- Lactose I.P. (Stabilizer).....5 mg
- Thimerosal I.P.(Preservative).....0.05 mg

8.2 Incompatibilities:

Not applicable

8.3 Shelf life :

24 months from the date of manufacture.

9. Nature and Contents of Container (Packing Information):-

i. Materials used for the containerization of vaccine are as follows:

- **Glass Vials :**

  2ml and 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-17) aluminium seal.

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

- **Glass vial :**

  2 ml and 5 ml, 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 with liquor.

9.1 Storage and Handling Instructions:

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

9.1.1 Special precaution for storage:

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 been passed.

9.1.2 Special precautions for disposal:

No special requirements

10. Patient Counselling Information:-

•Medical practioners/Healthcare professional can provide Diphenhydramine hydrochloride/ pheniramine maleate 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.

11. Marketing authorization Holder (Details of Manufacturer) :-

BIO-MED (P) LTD.
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pharmacovigilancebm@gmail.com
Website : www.biomed.co.in

12. Details of Marketing authorization number(s) (Details of Permission or License Number with Date) :-

- **Marketing authorization number:**

  Form 46 Permission No.: MF – 1752/04 dated 23/09/2004.

- **Date of first authorization/Renewal of the authorization : -**

  a) NOC for IP Specification vide F. No. X11031/28/09 D dated 30/06/2009.

  b) Additional item license No. vide letter No. Drug/837/8324 dated 01/07/2010.

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

13. Date of Revision:-

January, 2025.