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

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 :-

Meningococcal Polysaccharide Vaccine (Group A,C,Y &W135)
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)…….....0.01%

3. Pharmaceutical Form :-

Meningococcal Polysaccharide Vaccine (Group A, C, Y & W135) is a lyophilized vaccine.

4. Clinical Particulars :-

4.1 Therapeutic Indications:

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 also recommended for subjects living in closed communities and close contact of patients/carriers of Meningococcal Group A, C, Y & W135.

4.2 Physiology 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 Quadri Meningo™ elicits a significant bactericidal antibody response in about 100% of 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 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 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.

Precaution for use :

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.

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 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 Pharmacodynamics Properties:

Not applicable.

5.2 Pharmacokinetic Properties:

Not applicable

5.3 Preclinical Safety Data:

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.

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^{o}C to + 8^{o}C in the refrigerator.

6.5 Nature & contents of container:

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

- **Glass Vials :**

  2 ml 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.

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.

6.6 Special precautions for disposal:

No special requirements

7. Marketing authorization Holder :-

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

8. Marketing authorization number :-

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

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

a) Additional item license No. XXF/837/11403 dated 14/10/2004.

b) Renewal of authorization on Form 26-H dated 21/05/2014.

10. Date of Revision of the text :-

January, 2024