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

Meningococcal Polysaccharide Vaccine (Group A, C, Y & W135) I.P.
Brand name: - Quadri Meningo™

2. Qualitative and Quantitative Composition

Each dose (0.5 ml) of vaccine contains:-

- Purified Polysaccharide of Neisseria meningitidis

  - Group A.....50 mcg
  - Group C.....50 mcg
  - Group Y.....50 mcg
  - Group W135.....50 mcg

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

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, 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 Posology and method of administration:-

- Administer the vaccine (0.5ml) by intramuscular or subcutaneous route. 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.
- Administration of single 0.5 ml dose of Quadri Meningo™ elicits a significant bactericidal antibody response in about 100% if 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 and to lesser extent for the serogroups W135 and Y. However, the seroconversion rate for serogroup A is acceptable in children from the age of 6 months onwards.

4.3 Contra indications:-

- Hypersensitivity to any of the vaccine component.
- Ongoing acute or chronic illness like fever, severe infection, persistent diarrhoea, 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 for powder/pellet integrity. The vaccine after reconstitution should be shaken gently and visually inspected for any foreign particulate matter. In the event of the above, being observed discard the vaccine.
- As with other vaccinees, 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 vaccines 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.

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

Separate injection site must be used in case of concomitant vaccine administration.

No interaction studies of Quadri Meningo^{TM} with other vaccine have been performed.

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:-

The Quadri Meningo^{TM} vaccine has no effects after vaccination on ability to drive and use machines. No separate studies was done.

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:-

No cases of over dose have been reported.

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 preclinical safety Data the Quadri Meningo™ vaccine is found safe and a wide margin range of safety.

6. Pharmaceutical Particulars :-

6.1 List of excipients:-

Lactose I.P.
Thimerosal I.P.

6.2 Incompatibilities:-

No compatibility studies of Quadri Meningo™ vaccine with other vaccine was done.

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

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 final packing of vaccine are as follows.

- Glass Vials :-

  2ml and 5 ml, 13 mm USP type I clear tubular glass vial for single and multi-dose.

- Rubber closures :-

  13 mm Grey Butyl Slotted Rubber Stopper (Sterile ready for use).

- Aluminium Seals :-

  13 mm flip off GN-17 aluminium seals.

Materials used for the final packing of vaccine diluent are as follows:

- Glass vial :-

  2ml and 5 ml, 13 mm USP type I clear tubular glass vial for single and multi

dose diluent.

- Rubber Closures: -

  13 mm Grey butyl, 'Bioclean RFU' Rubber stopper.

- Aluminium Seals :-

  13 mm flip off white (WE1) aluminium seals.

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 :-

Permission No.MF-1752-04 (Form 46) dated 23/09/2004

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

a) **First authorization:** License No. 05/LVP/Sera & Vaccines/2004 on Form 28-D dated 01st July, 2010.
b) **Renewal of authorization** License No. 05/LVP/Sera & Vaccines/2004 on Form 26-H dated 21 May 2014.

10. Date of Revision of the text:-

May, 2017.