Summary of Product Characteristics of Typhoid Polysaccharide Vaccine I.P.

Brand Name : Bio Typh™

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 :-

Typhoid Polysaccharide Vaccine I.P.
Brand Name: Bio Typh™

2. Qualitative & Quantitative Compositions :-

One Dose (0.5ml) contains:

Vi polysaccharide of *Salmonella typhi* (Strain Ty2)……..25µg
Phenol I.P. (Preservative)……max. 0.25%
Isotonic saline (buffered) q.s……..0.5ml

3. Pharmaceutical Form :-

Bio Typh™ is a clear solution containing purified Vi capsular polysaccharide of Salmonella typhi (Strain Ty2) for prevention of Typhoid fever

4. Clinical Particulars :-

4.1 Therapeutic Indications:

- Adults and Children over 2 years of age
- Travellers proceeding to endemic areas
- Mela /fair visitors
- Vendors of unprotected food
- Settlers in poor hygienic areas

4.2 Physiology and method of administration:

- Inject 0.5 ml in adults and children over 2 years of age by intramuscular or subcutaneous route. It should under no circumstances be administered intravenously.
- Vaccine provides protection for a period of three years.
- Re-immunization every three years under conditions of repeated or continued exposure is recommended.
- Prevention becomes effective 2-3 weeks after immunization.

4.3 Contra-indication:

- Hypersensitivity to any constituent of the vaccine.
- Pregnant and lactating women.
- In the event of fever or severe infection, diarrhoea, dysentery, debilitating ailment, abdominal pain etc.

4.4 Special warnings and precaution 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 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.

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

Not applicable

4.6 Pregnancy & Lactation:

Not applicable

4.7 Effects on ability to drive and use machines:

Not Applicable

4.8 Undesirable effects:

Mild local pain, redness, induration & fever may occur during the 48 hours following injection. Paracetamol or ibuprofen cover for 36 hours after vaccination shall decrease the intensity of side effects

4.9 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 preclinical safety Data the Bio Typh™ was found safe.

6. Pharmaceutical Particulars :-

6.1 List of excipients:

Each dose (0.5 ml) of vaccine contains:-

Phenol I.P.(Preservative)……..……max. 0.25%
Isotonic saline (buffered) q.s……...0.5ml

6.2 Incompatibilities:

Not applicable

6.3 Shelf life:

Use the product within 30 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.

i) Glass Vials:

2 ml, 13 mm clear tubular type I glass vial for single dose & 5 ml, 13 mm clear tubular type 1 glass vial for multi dose.

ii) Rubber closures :

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

iii) Aluminium Seals :

13 mm flip off BE-11 aluminium seals.

iv) Prefilled syringe :

USP Type-1 prefilled syringe with fixed needle.

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 – 123/2014 dated 02/06/2014 and amendment for Form 46 vide F. No. 12-09/BIOMED/14-BD dated 19/12/2014.

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

a) NOC for Additional items vide F. No. X.11031/8/97-D dated 31/07/1998.

b) Additional item license No. vide letter No. 20F/837/11307 dated 23/12/1998.

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

d) Additional item license No. vide letter No. Drug/837/8374 dated 01/07/2010.

e) Additional item license No. vide letter No. Drug/837/717 dated 23/01/2015.

f) Additional item license No. vide letter No. Drug/837/3286 dated 19/05/2017.

g) Additional item license No. vide letter No. Drug/837/4795 dated 24/08/2017.

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

10. Date of Revision of the text:-

January, 2024