

Summary of Product Characteristics OF

Vi Polysaccharide Typhoid Vaccine

Brand Name: Bio TyphTM

Manufactured By:

BIO-MED (P) LTD.
C-96, Site No. 1,
Bulandshahr Road Industrial Area,
Ghaziabad - 201 009 (U.P.) INDIA
Phone : 0120-4157534, 4204862
Fax : 0120-4340219
e-Mail : bmvaccine@yahoo.com
Website: www.biomed.co.in

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

1. Name of the Medicinal product :-

Vi Polysaccharide Typhoid Vaccine
Brand Name: Bio Typh™

2. Qualitative & Quantitative Compositions :-

One Dose (0.5 ml) contains:

Vi polysaccharide of Salmonella typhi25mcg
Phenol I.P. (Preservative).....max. 0.25%
Isotonic saline q.s.....0.5ml

3. Pharmaceutical Form :-

Bio Typh™ is a clear solution.

4. Clinical Particulars :-

4.1 Therapeutic Indications:-

For prevention of Typhoid fever.

4.2 Posology and method of administration:-

- Inject 0.5 ml in adults and children over 2 years of age by intramuscular or subcutaneous route.
- Vaccine provides protection for a period of three years.
- Reimmunization 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.

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 appropriate medical treatment, epinephrine injection (1:1000) must be immediately available, should be acute anaphylactoid reaction occur due to any

component of the vaccine. The vaccinee should remain under medical supervision for not less than 30 minutes after vaccination.

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 and 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 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:-

Isotonic saline

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. Do not freeze.

6.5 Nature & contents of container:-

Various material used for the final packing 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.

• Rubber closures :-

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

• Aluminium Seals :-

13 mm flip off BE-11 aluminium seals.

ii) 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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8. Marketing authorization number:-

Permission No.MF – 123/2014 (Form 46) Dated 02/06/2014

Date of first authorization/Renewal of the authorization:-

- a) **First authorization:** License No. 15/SC/P/1974 F. No. X.11031/8/97-D dated 31st July 1998.
- b) **Renewal of authorization:** License No. 05/LVP/S&V/2004 on Form 28-D dated 20th March 2004.
- c) **Renewal of authorization:** License No. 05/LVP/S&V/2004 on Form 26-H dated 01 July 2008.
- d) **Renewal of authorization:** License No. 05/LVP/S&V/2004 on Form 26-H dated 21 May 2014.
- e) Validity Certificate No.: Drug/837/3160 dated 16/05/2017

9. Date of Revision of the text:-

May, 2017.