Summary of Product Characteristics of Typhoid Vi Conjugate Vaccine I.P.

Brand Name: Peda 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 Vi Conjugate Vaccine I.P.
Brand Name: Peda Typh™

2. Qualitative & Quantitative Compositions :-

One dose (0.5 ml) contains :-

5 µg of Vi polysaccharide of *Salmonella typhi* (Strain Ty2) conjugated to 5 µg Tetanus toxoid protein in isotonic saline 0.5 ml.

3. Pharmaceutical Form :-

A clear to slightly turbid solution containing purified Vi capsular polysaccharide of *Salmonella typhi* (Strain Ty2) conjugated to 5 µg Tetanus toxoid protein.

4. Clinical Particulars :-

4.1 Therapeutic Indications:

PedaTyph™ is indicated for active immunization against *Salmonella typhi* in infants of age ≥3 months, children and adults.

4.2 Physiology and method of administration:

- Inject 0.5 ml intramuscularly. Do not inject intravenously or intradermally.
- Prevention becomes effective 4 weeks after immunization.

Dosage:-

- One dose followed by a booster after $2^{1/2}$ - 3 years of primary vaccination. Vaccination can be done 3 months age onwards.

4.3 Contra indication:

- Hypersensitivity to any constituent of the vaccine.
- Pregnant and lactating women.
- In the event of fever, severe infection, persistent diarrhea & vomiting.

4.4 Special warnings and precaution for use:

The vaccine should be 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 vaccine 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.

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:

As for any product, there may be more or less moderate and temporary side effects like:

- Pain, induration, erythema, pruritus at the injection site.
- Rare, transient febrile reactions.
- 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.

5.2 Pharmacokinetic Properties:

Not applicable.

5.3 Preclinical Safety Data :

In the Animal Toxicity studies, no abnormal or adverse effects due Typhoid Vi Conjugate Vaccine were noted in animals during the acute toxicity studies as well as long term toxicity studies. The Typhoid Vi Conjugate Vaccine has passed the Animal Toxicity studies in animals.

6. Pharmaceutical Particulars :-

6.1 List of excipients :-

One dose (0.5 ml) of vaccine contains following excipients:-

Isotonic saline (IP) ……0.5ml

6.2 Incompatibilities:-

Not applicable

6.3 Shelf life:-

The shelf life of the product is 36 months from the date of manufacture if stored at recommended storage conditions.

6.4 Special precaution for storage:-

Store between +2^{o}C to + 8^{o}C in the refrigerator. Do not freeze, discard if the vaccine has been frozen.

6.5 Nature & contents of container:-

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

i) Glass Vials :

2 ml clear tubular glass vial (USP type I)

ii) Rubber closures :

13 mm Non Slotted Grey Butyl Unister RFU Sterile Rubber Stopper

iii) Aluminium Seals :

13 mm flip off blue (BE-37) aluminium

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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pharmacovigilancebm@gmail.com
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8. Marketing authorization number:-

Form-46 Permission No. MF –528/08 dated 09/05/2008.

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

a) Additional items vide F. No. 20F/837/6820 dated 01/07/2008.

b) NOC for IP Specification vide F. No. 12-146/Biomed/PAC-Typhoid/16-BD dated 19/12/2016.

c) NOC for Additional item license No. vide letter No. 12-01/Bio-Med/PAC-Typhoid Vi Conjugate/17-BD dated 17/03/2017.

d) Additional item license No. vide letter No. Drug/837/3285 dated 19/05/2017.

e) Additional item PFS license No. vide letter No. Drug/837/4794 dated 24/08/2017.

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

10. Date of Revision of the text:-

January, 2024.