

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 :-

Typhoid Vi Conjugate Vaccine I.P. is a clear solution.

4. Clinical Particulars :-

4.1 Therapeutic Indications:-

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

4.2 Posology and method of administration:-

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

4.3 Contra indication:-

- Hypersensitivity to any constituent of the vaccine.
- Pregnant & lactating women.
- In the event of fever, severe infection, persistent diarrhoea & 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 life saving. It should be used at the first suspicion of anaphylaxis. The vaccinees 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 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 Peda Typh™ was found safe.

6. Pharmaceutical Particulars :-

6.1 List of excipients:-

Isotonic saline

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°C to + 8°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 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 m Grey butyl, 'Bio clean RFU' Rubber stopper.

Aluminium Seals :-

13 mm flip off BE-37 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:-

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8. Marketing authorization number:-

Number of permission MF-528/08 dated 09/05/2008 issued on Form-46. Further we have received NOC to manufacture Typhoid Vi Conjugate Vaccine as per Indian Pharmacopoeia from DCGI Vide Letter File No. 12-146/Biomed/PAC-Typhoid/16-BD Dated 19/12/2016.

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

- **First authorization:** -The product was licensed on Form 28D License No. 05/LVP/S&V/2004 permission issued on 1st July, 2008
- **Renewal of authorization:** -License No. 05/LVP/S&V/2004 on Form 26-H dated 21 May, 2014.
- Addition item permission for Typhoid Vi Conjugate Vaccine I.P. on Form 28D License No. 05/LVP/S&V/2004 permission issued on 19/05/2017
- Validity Certificate No.: Drug/837/3160 dated 16/05/2017.

10. Date of Revision of the text:-

May, 2017