

Typhoid Vi Conjugate Vaccine I.P.

Peda Typh™

DESCRIPTION & INDICATION

A clear to slightly turbid solution containing purified Vi capsular polysaccharide of *Salmonella typhi* (Strain Ty2) conjugated with Tetanus toxoid protein for prevention of typhoid fever.

Peda Typh™ is manufactured as per Indian pharmacopoeia. The manufacturing facilities meets the requirements as per cGMP guidelines of revised schedule 'M' of the Drugs & Cosmetic Act, Government of India and W.H.O. G.M.P. guidelines.

COMPOSITION

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.

INDICATIONS

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

CONTRA-INDICATION

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

PRECAUTIONS

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 vaccinee 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.

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 2½-3 years of primary vaccination. Vaccination can be done 3 months age onwards.

POSSIBLE SIDE 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.

STABILITY

Vaccine have been found to be stable for atleast 3 years when stored at +2° to +8°C and for 3 months when kept at 20° to 25°C or 30° to 35°C.

STORAGE

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

PRESENTATION

- One dose in glass vial with disposable syringe.
- One dose in pre-filled syringe.

SHELF LIFE

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

CLINICAL TRIALS

Several pre and post licensure clinical trials conducted on Peda Typh™ establishes its safety, immunogenicity and efficacy. Efficacy of the vaccine have been found to be 100%.

References :-

1. Garg P., Garg S., Sharma M. K.
Clinical trial of Tetanus Toxoid Conjugated Vi Polysaccharide Typhoid Vaccine in infants and young children.
Sharma et al (2014) Biotechnology International 7(4) : 90-100
2. Chinnasami B., Mangayarkarasi V., Prema A., Sadasivam K. & Davis M. J.
Safety and Immunogenicity of *Salmonella typhi* Vi conjugate vaccine (Peda Typh™) in children upto five years.
International Journal of Scientific and Research Publications, Volume 3, Issue 2, February 2013
3. Chinnasami B., Sadasivam K., Vivekanandhan A., Arunachalam P. & Pasupathy S.
A Study on Longevity of Immune Response after Vaccination with *Salmonella typhi* Vi Conjugate Vaccine (Peda Typh™) in Children. Journal of Clinical & Diagnostic Research. 2015 May, Vol-9(5) : SC01-SC03.
4. Mitra M., Shah N., Ghosh A., et al.
Efficacy and safety of vi-tetanus toxoid conjugated typhoid vaccine (Peda Typh™) in Indian children : School based cluster randomized study. Human Vaccines & Immunotherapeutics 2016, Vol.0, No. 0, 1-7

Manufactured & Marketed by :



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