For the use of Registered Medical Practitioner or Hospital or a Laboratory only

Typhoid Polysaccharide Vaccine IP

TYPBAR®

1. NAME AND DESCRIPTION OF THE MEDICINAL PRODUCT

Typbar® is a sterile solution containing the capsular Vi capsular polysaccharide of *Salmonella enterica* serovar *typhi Ty2 strain.*

Vi Capsular polysaccharide of *Salmonella typhi* elicit B cell responses.

Typbar® protects against typhoid fever caused by *Salmonella typhi* Ty2. Protection is not conferred against *Salmonella paratyphi* and other non-typhoidal *Salmonellae* causing typhoid infection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 0.5 mL contains	
Purified Vi Capsular Polysaccharide of *Salmonella typhi Ty2*	25 µg
Phenol IP	NMT 0.25% w/v
Phosphate Buffered Saline	q.s. to 0.5mL

3. PHARMACEUTICAL FORM

Sterile Solution for Injection.

4. CLINICAL PARTICULARS

4.1 Prophylactic Indications

Typbar® is indicated in children above 2 years of age and adults for active immunization against *Salmonella typhi* infection.

In addition, for various groups of individuals listed below, **Typbar®** immunization is an essential requirement:

- Healthcare personnel
- Travelers to specified high endemic areas.
- Residents in high endemic area.
- Personnel and residents of community homes or hostels
- Police and military personnel

4.2 Posology and Method of Administration

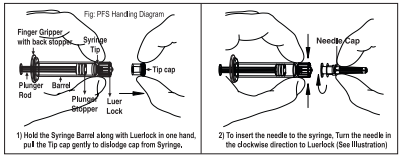
Inject 0.5 mL intramuscularly.

- Primary Series (first dose): 1 dose (0.5mL) in children above 2 years of age and adults.
- Booster Dose : A booster dose (0.5mL) should be given within three years after first dose

Typbar® should be given intramuscularly in the deltoid (upper arm) muscle in adults and in children in the vastus lateralis (anterolateral thigh) up to 12 years of age.

PFS Handling Procedure: Prior to administration, ensure that the plunger rod is firmly attached to the rubber stopper by turning the plunger rod clockwise until slight resistance is felt. Do not over tighten. Remove rubber tip-cap from the syringe and fix the needle on syringe by turning in clock wise direction into Luer-lock until it is securely fixed to the syringe, remove the needle cap before injecting. Do not rotate Luer-lock. Finger grip with back stopper will prevent plunger rod coming out from the syringe barrel. Do not remove the back-stopper from the syringe.

Fig: PFS Handling Diagram



4.3 Contraindications

- Hypersensitivity to any constituent of the vaccine.
- Pregnant & lactating women.
- During fever or severe infection.

4.4 Special Warning and Precautions

- Do not administer intravenously, intradermally, or subcutaneously.
- Like all other vaccines, supervision and appropriate medical treatment should always be available to treat any anaphylactic reactions following immunization.
- Epinephrine injection (1:1000) must be immediately available in case of an acute anaphylactic reaction or any allergic reaction occuring due to any component of the vaccine.
- The vaccinee should remain under medical supervision for at least 30 minutes after vaccination.

4.5 Interaction with other medicinal products and other forms of interaction

With some exceptions (such as pneumococcal- and meningococcal-conjugate vaccines), all commonly used vaccines can safely and effectively be given simultaneously (on the same day) at separate sites without impairing antibody responses or increasing rates of adverse reactions. The immune response to an injected or intranasal live-virus vaccine (such as varicella, yellow fever, or live attenuated influenza vaccines) might be impaired if administered within 28 days of another live-virus vaccine (within 30 days for yellow fever vaccine). Whenever possible, injected live-virus vaccines administered on different days should be given ≥28 days apart (≥30 days for yellow fever vaccine).

4.6 Pregnancy and Lactation

Safety has not been established in pregnant women and in nursing mothers.

4.7 Effect on ability to drive and use machines

No studies on the effect of **Typbar®** on the ability to drive and use machines have been performed.

4.8 Undesirable effects

Clinical Trial Experience

A multi-centre, double-blind, randomized, parallel, phase 3 study was conducted to evaluate the safety and immunogenicity of **Typbar®** in comparison with a marketed vaccine as a prophylactic vaccine for typhoid fever in healthy subjects. The common local symptoms in both the vaccine groups were pain and redness at injection site. The rare general symptoms were fever and headache. The symptoms resolved in 48 hours with symptomatic treatment. No adverse events were observed/ recorded during the first 30 minutes. The assessment of immunogenicity was carried out by the measurement of anti Vi antibody by sandwich ELISA technique. The clearly demonstrates the immunogenicity of **Typbar®** by inducing strong immune response to the injected antigens. 71.81 % of the subjects were seroconverted by day 30. These results were comparable to that of the results in terms of immunogenicity of Reference vaccine.

Post Marketing Experience

The most common adverse events noted were fever and pain at injection site. The other minor adverse reactions noted were vomiting, Redness & swelling, rashes, excessive crying, loss of appetite, Irritability, headache, Common cold, diarrhoea and nausea & vomiting. None of these subjects required hospitalization.

4.9 Overdose

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Typhoid fever is a very common and serious bacterial disease caused by *Salmonella typhi.* Vi polysaccharide vaccine is immunogenic and is T-cell independent which induces Vi antibodies that neutralize Vi antigen and hence prevents the infection

5.2 Pharmacokinetic Properties

Evaluation of pharmacokinetic properties is not required for vaccines.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

- Phenol IP
- Phosphate Buffered Saline

6.2 Incompatibilities

This vaccine must not be mixed with other medicinal products.

6.3 Shelf Life

The expiry date of the vaccine is indicated on the label and carton of the product

6.4 Special Precautions for Storage

Store at +2°C to +8°C. Do not freeze. Discard if frozen.
Shake well before use.
Keep out of reach of children. Protect from light.
Do not use the vaccine after the expiration date shown on the label.

Using a sterile syringe fitted with a sterile needle, a single dose is withdrawn from the multi-dose vial, after disinfecting the outer surface of the vial stopper using a disinfectant. For the subsequent dose(s), the same operation in other subjects should be repeated using different syringe each time to vaccinate. Between the different withdrawal operations and, in any case, within not more than 5 minutes after the last dose withdrawal, the vial should be replaced in a refrigerator to keep the product at its normal storage temperature between +2°C to +8°C (never place it in a freezer).

7. PRESENTATION

Typbar® is presented in USP type 1 glass vial and Pre-filled Syringe

- Single dose Vial: 0.5 mL
- Single dose PFS: 0.5 mL
- Multi dose Vial: 2.5 mL
- Multi dose Vial: 5.0 mL

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Manufactured & Marketed by:

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