For use by a registered medical practitioner or hospital or laboratory only

Vi Capsular Polysaccharide Typhoid Vaccine I.P

TYPBAR®

Description
TYPBAR® is a sterile solution for intramuscular use containing the cell surface Vi polysaccharide extracted from salmonellatyphi Ty2 strain. The vaccine appears as a clear, colourless solution.

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

CLINICAL PARTICULARS
Therapeutic indications
TYPBAR® is indicated for active immunization against typhoid Fever for both adults and children two years of age or older.

Selective immunization with **TYPBAR®** is recommended for the Following:

- Traveler's to high endemic areas
- Household contacts of carriers
- Healthcare personnel
- Police, Armed forces and such other regimented Personnel.

Contraindications
TYPBAR® should not be administered to subjects with known hypersensitivity to any component of the vaccine or to subjects having shown signs of hypersensitivity after a previous administration.

Dosage
The immunizing dose for adults and children 2 years of age and older is a single dose 0.5mL.

Subjects who remain at risk of typhoid fever should be given a single booster dose of the vaccine with an interval of not more than 3 years.

Method of administration
TYPBAR® is for intramuscular injection only. DO NOT inject intravenously.

TYPBAR® in adult should be given intramuscularly in the deltoid and children should be injected intramuscularly either in the deltoid or the vastus lateralis. **TYPBAR®** should not be injected into the gluteal area or areas where there may be a nerve trunk.

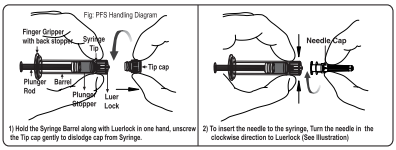
While using the multi-dose vial, care must be taken to use separate sterile and syringes and needles for the administration of every dose.

Before use, **TYPBAR®** should be well shaken. Vaccine should be visually checked for the presence of any particulate matter or other coloration, if any, prior to its administration. If in doubt, do not use the contents of the vial.

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. Hold the Syringe Barrel along with Luer-lock in one hand, unscrew the Tip cap gently to dislodge cap from 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



1) Hold the Syringe Barrel along with Luerlock in one hand, unscrew the Tip cap gently to dislodge cap from Syringe.

2) To insert the needle to the syringe, Turn the needle in the clockwise direction to Luerlock (See Illustration)

Special Precautions and Warning for Use
TYPBAR® protects against typhoid fever caused by Salmonella typhi. Protection is not conferred against Salmonella Paratyphi and other non-Typhoidal Salmonellae.

Adrenaline injection must be kept readily available following immunization should an anaphylactic or other allergic reaction occur due to any component of the vaccine

The administration of **TYPBAR®** should be delayed in subjects with acute infection or febrile illness.

TYPBAR® should be administered with caution to subjects with thrombocytopenia or bleeding disorders since bleeding may occur following an intramuscular administration in these subjects. It may be expected that in patients receiving immunosuppressive treatment or patients with immunodeficiency, an adequate response may not be achieved.

TYPBAR® should not be mixed with other vaccines or medicinal products in the same syringe.

Pregnancy
The effect of the **TYPBAR®** on fetal development or reproduction capacity has not been evaluated.

TYPBAR® should be given to a pregnant woman only if clearly needed.

Nursing Mothers
It is not known if **TYPBAR®** is excreted in human milk. It may be administered to nursing mothers only if clearly needed.

Paediatric Use
Safety and effectiveness of **TYPBAR®** in children 2 years of age and below has not been established. Polysaccharide vaccines in general have lower immunogenicity under this age.

ADVERSE REACTIONS
Most recipients of typhoid vaccine experience some reactions upon vaccination. These are generally moderate and short in duration. They mainly consist of local reactions at the injection site (erythema, induration and tenderness). Systemic reactions (malaise, headache, diarrohoea, vomiting myalgia and elevated temperature) are reported less commonly.

In very rare cases, allergic - type reactions (pruritus, rash urticaria) may be observed.

PHARMACEUTICAL PARTICULARS:

Category	: Active immunizing agent.
Pharmaceutical form	: Liquid for injection.
Shelf life	: 3 years from the date of manufacture.
Storage	: at 2°C to 8°C.

DO NOT FREEZE. DISCARD IF FROZEN.
KEEP OUT OF REACH OF CHILDREN.

PRESENTATION:
TYPBAR® is presented in USP type 1 glass vial and PFS

Single dose	: 0.5 mL.
Multi-dose	: 2.5 mL.
Multi-dose	: 5.0 mL.
Single Dose PFS	: 0.5 mL.

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Manufactured & Marketed by :

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For complaints and suggestions about the product, and any adverse event,
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