SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE MEDICINAL PRODUCT:

Name of the product: Typhoid Polysaccharide Vaccine IP
Strength: Each dose of 0.5 mL Contains:
Purified Vi Capsular Polysaccharide of *Salmonella* typhi Ty2: 25 µg
Pharmaceutical Form: Vaccine (Liquid)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

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
Vaccine (Liquid)

4. CLINICAL PARTICULARS
4.1 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.

4.2. Posology and method of 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.

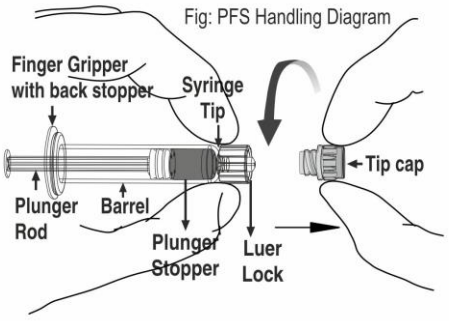
While using the multi-dose vial, care must be taken to use separate sterile and syringes and needles for the administration of every dose.

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.

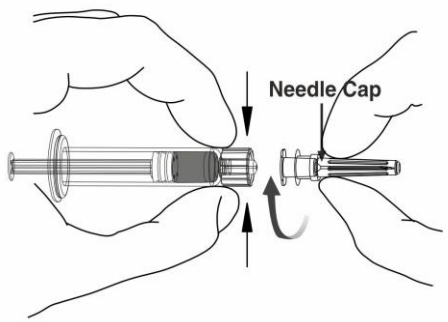
PFS Handling procedure:
Prior to administration, ensure that the plunger rod is firmly attached to the rubber stopper by turning the plunger rod clockwise until slight resistance is felt. Do not over tighten. Hold the Syringe Barrel along with Luer-lock in one hand, unscrew the Tip cap gently to dis-lodge 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)

4.3 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.

4.4 Special warning and Precautions 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.

4.5 Interaction with other medicinal products/active immunising agents and other forms of interaction

No interaction studies have been performed.

4.6. Pregnancy and lactation

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.

4.7. Effect on ability to drive and use machines
Not applicable.

4.8 Undesirable effects
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, diarrhoea, vomiting myalgia and elevated temperature) are reported less commonly.

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

4.9. Overdose
No data available

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Not Applicable

5.2 Pharmacokinetic properties
Evaluation of pharmacokinetic properties is not required for vaccines.

5.3 Pre-clinical safety data
Not Applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
TYPBAR® contains Phenol IP and Phosphate Buffered Saline.

6.2 Incompatibilities
The vaccine should not be mixed with any other medicinal products or active immunizing agents.

6.3 Shelf life
The expiry date of TYPBAR® is indicated on the label and carton of the vaccine.

6.4 Special Precautions for Storage
The recommended storage temperature for TYPBAR® is 2°C to 8°C.
do not freeze. discard if frozen. keep out of reach of children.

6.5 Nature and contents of container
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.

6.6 Special precautions for disposal
Any unused product or waste material should be disposed of in accordance with local

requirements.

7. MARKETING AUTHORISATION HOLDER

BHARAT BIOTECH Lead Innovation

Bharat Biotech International Limited situated

Sy. No. 230, 231 & 235, Genome Valley,

Turkapally, Shamirpet Mandal,

Medchal, Malkajgiri District, Telangana State, India, Pin: 500078.

8. MARKETING AUTHORISATION NUMBER
F.No: 12-3/2002-DC

9. DATE OF FIRST MARKETING AUTHORISATION
23 JAN 2003

10. DATE OF REVISION
JUNE 2024

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