Typhbar-TCV Pack insert

For use only by a Registered Medical Practitioner or Hospital or Laboratory

Typhov (V) Capsular Polyosaccharide-

Tetanus Toxoid Conjugate Vaccine

**Typhbar-TCV**

1. NAME AND DESCRIPTION OF THE MEDICINAL PRODUCT

Typhov-TCV** is a killed, cell-cultured, liquid containing porcine 

V. cholerae capsular polysaccharide and Salmonella typhi Vi 

antigen linked to tetanus toxoid protein vaccine.

This is a tetanus toxoid which induces an antibody that reacts with 

vi antigen linked to tetanol-tetradye protein vaccine.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

For single dose (1 ml):

- For oral use (oral): 5 ml
  - For oral use (oral): 5 ml
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3. PHARMACEUTICAL FORM

A clear, colorless liquid for intramuscular injection.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Typhov-TCV** is indicated for active immunization against salmonella 

type infection in adults, children and infants of age of 5 months and 

above.

4.2 Pharmacology and Method of Administration

Intact 0.5 ml of Typhov-TCV** is administered as an intramuscular 

injection in the deltoid or the vastus lateralis muscles of 2 doses of 

2 ml each 3-4 weeks after vaccination.

4.3 Dosage & Schedule

The immunizing dose for adults, children and infants of age of 5 months and 

above is 0.5 ml, the booster does may be given after 3 years.

4.4 Contraindications

- Hypersensitivity to any component of the vaccine.
- Pregnancy or lactation of women.
- In the event of fever or severe infection.

4.5 Special Warning/Precautions

- Do not administer intravenously, intramuscularly or subcutaneously.
- Intraocular injection of Typhov-TCV** is not recommended by Salmonella.
- Vaccine should be visually checked for the presence of any 

pallidum or other particulate matter. Do not use the contents of the 

vials if cloudy or sedimented.
- Expiration date of 5 years must be immediately available in 

case of an emergency when vaccine or antibody administration 

may be life-saving. If vaccine is required under medical supervision it must be 8-12 months 

after expiration. Use of all vaccine, especially in at-risk 

populations, should always be performed to the pathogenic vaccine following recommendations.
- Typhov-TCV** should not be mixed with other vaccines 

or other products in the same syringe.

4.6 Interaction with other medicinal products or other forms of 

immunization

For concurrent or co-administration use different injection sites 

and products. Typhov-TCV** should not be mixed with any other 

vaccine or medicae product, because the interactions with other 

immunization products has not been established.

4.7 Pregnancy and Lactation

Safety and effectiveness data have not been established in pregnant 

women and lactating mothers. It is not known whether this vaccine is excreted in 

human milk.

4.8 Effectiveness of this vaccine and use method

No studies or studies on the effect of Typhov-TCV** on the ability to drive and use 

machine have been performed.

4.9 Undesirable Effects

The safety of Typhov-TCV** vaccine was established in a controlled 
clinical trial in children to 6 months to 15 years of age and adults of age of 5-65 years.

Within each group, adverse reactions were ranked under headings of frequency using the following convention:

- Frequent, (>10%)
- Infrequent, (1% to 10%)
- Rare, (<0.1%)

4.10 Overdosage

No cases of overdosage have been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Typhov-TCV** is a very common and severe bacterial disease caused by 

Salmonella typhi. All conjugate vaccines have shown to be efficacious 

and immunogenic. Typhov-TCV** is a vaccine that induces a long-lasting 

immunity and provides protection against the disease.

5.2 Clinical Studies

During Phase III clinical study after a single dose of Typhov-TCV**, 

percentage of seroconversion of 94% and their mean antibody 

levels between 12 months and 60 years of age were studied at 66.6% in 12-24 months, 60% at 25-36 months, 76% at 37-48 months, and 82% at 49-60 months.

5.3 Pharmacokinetic Properties

Evaluation of pharmacokinetic properties is not required for vaccines.

6. PHARMACOLOGICAL PARTICULARS

6.1 List of excipients

- Sodium chloride
- 2-Phenoxethanol 0.012 mg/ml 

6.2 Important information

This medical product must be mixed with other medical products.

6.3 Shelf Life

2 years from the date of manufacture.

6.4 Special Precautions for Storage 

Store at refrigerated temperature of 2°C to 8°C (36°F to 45°F), 

DO NOT FREEZE. DISCARD FROZEN, REWORKED OR REHEATED PRODUCTS.

Do not use the vaccine after the expiration date shown on the 

label. Solutions should be used within 5 min when stored under refrigeration 

at 2°C to 8°C (36°F to 45°F) for 30 min, and 30 min. for 2°C to 8°C (36°F to 45°F) for 30 min.

Ensure that the vaccine is mixed with other vaccines at the same time or subsequent.

7. PRESCRIPTION

Typhov-TCV** is administered in USP type 1 glass vial and 

Pyrex glass vial and

- Single dose: 0.5 ml
- Single dose: 0.5 ml
- Multidose: 2.5 ml

Manufactured & Marketed by Bharat Biotech International Ltd., 

Gujarat Medical, Gujarat, India.

Date: 12-07-2013

Approval

Technical Expert: CRD, QA/RA, QC, QA, Production & Mktg.

Sign: 90% Black C

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