SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

Typhoid VI Conjugate Vaccine
TYPBAR TCV (0.5ml single dose vial)

Typhoid VI Conjugate Vaccine
TYPBAR TCV (0.5ml prefilled syringe)

Typhoid VI Conjugate Vaccine
TYPBAR TCV (2.5ml 5-dose vial)

2. Qualitative and quantitative composition

Typbar TCV® is a sterile clear and colorless liquid containing purified VI Capsular Polysaccharide of *Salmonella typhi* Ty2 which is conjugated to Tetanus Toxoid carried protein.
This is T-cell dependent which includes VI antibodies that neutralize VI antigen unlike T-cell independent plain VI polysaccharide vaccines.
Typbar TCV® can be administered to infants to age ≥ 6 months, children and adults as a single dose intramuscularly. The complete qualitative and quantitative composition of Typbar TCV® is given below:
For single dose (0.5 mL)
Each 0.5 mL of dose contains:
Purified Vi-Capsular Polysaccharide of
S. typhi Ty2 conjugated to Tetanus Toxoid …….. 25 µg
Sodium chloride BP……... 4.5 mg
Water for injection BP…… q.s. to 0.5 mL
For multi dose (2.5 mL)
Each 0.5 mL of dose contains:
Purified Vi-Capsular Polysaccharide of
S. typhi Ty2 conjugated to Tetanus Toxoid ……25 µg
Sodium chloride BP……...
4.5 mg 2-Phenoxyethanol BP……
5.0 mg Water for injection BP…… q.s. to 0.5 m

3. Pharmaceutical form

A clear, to slightly turbid liquid for intramuscular injection.

4. Clinical particulars

4.1 Therapeutic indications

Typbar TCV® is indicated for active immunization against *salmonella typhi* infection in adults, children, and infants of age ≥ 6 months and above.

4.2 Posology and method of administration

The immunizing dose for adults, children, and infants of age ≥6 months is single dose of 0.5 mL; a booster dose may be given after 3 years. Inject 0.5mL intramuscularly. Typbar TCV® should be

given intramuscularly in the deltoid region or the vastus lateralis of children below two years of age. Typbar TCV® should not be injected into the gluteal area or areas where there may be a nerve trunk. Prevention becomes effective in 2 – 3 weeks of immunization.

4.3 Contraindications

- Hypersensitivity to any component of vaccine
- Pregnant & lactating women
- In case of fever and severe infection.

4.4 Special warnings and precautions for use

- Do not administer intravenously, intradermally or subcutaneously.
- Typbar TCV® protects against typhoid fever caused by *Salmonella typhi*. Protection is not conferred against *Salmonella paratyphi* and other non-typhoidal Salmonellae.
- Vaccine should be visually checked for the presence of any particulate matter. Do not use the contents of the vial if in doubt and discard it.
- Epinephrine injection (1:1000) must be immediately available in case of an anaphylactic reaction or any allergic reaction occurs due to any component of the vaccine. The vaccine should remain under medical supervision for not less than 30 minutes after vaccination. Like all other vaccine, supervision and appropriate medical treatment should always be available to treat any anaphylactic reaction following immunization.
- Typbar TCV® should not be mixed with other vaccines or medical products in the same syringe

4.5 Interaction with other medicinal products and other forms of interaction

For concomitant or co-administration use different injection sites and separate syringes. Typbar TCV® should not be mixed with any other vaccine or medical product because the interaction with other vaccines or medical product has not been established.

4.6 Pregnancy and lactation

Safety and effectiveness have not been established in pregnant women and in nursing mothers. It is not known whether the vaccine is excreted in human milk.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

The safety of Typbar TCV® vaccine was established in a controlled clinical trial in infant's ≥ 6 months to 2 years, in children and adults in the age group of > 2 to 45 years. Within each system organ class, the adverse reactions were ranked under heading of frequency using the following convention:

Very common:	≥ 10%
Common:	≥ 1% and < 10%
Uncommon:	≥ 0.1% and < 1%
Rare:	≥ 0.01% and < 0.1%
Very rare:	< 0.01%.

A total of 981 healthy subjects were enrolled into the study at 8 clinical sites. There were 2 cohorts in the study, cohort-I was single arm open label and 327 subjects were recruited between the age of ≥ 6 months to 2 years. All the subjects received single dose of Typbar TCV® vaccine. The cohort-II was randomised double blind trial and 654 subjects between > 2 years to 45 years were recruited who received single dose of either Typbar TCV® or comparator vaccine.
The most frequently reported adverse events after administration of Typbar TCV® fever and pain at injection-site. These usually occurred within the first 48 hours after vaccination and disappeared within 2 days.
General and administration site conditions:
- Common: Fever, pain at injection-site and swelling
- Uncommon: Tenderness, itching, arthralgia, cold, cough, vomiting and myalgia.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the e-PV desktop applications (https://drive.google.com/file/d/16hwTz0587ZWtSWadbBAMwQPOD_KSExZP/view) or search for e-PV Mobile applications on the Google Play or Apple App Store.

4.9 Overdose
No case of overdose has been reported.

5. Pharmacological properties
5.1 Pharmacodynamic properties
Pharmacological classification: 18.2 Vaccines

Typhoid fever is a very common and serious bacterial disease cause by *Salmonella typhi*. All conjugate vaccine studies have shown that the efficacy and immunogenicity are higher than the plain VI polysaccharide vaccine. In the manufacturing of Typbar TCV®, the VI polysaccharide has been conjugated with non-toxic tetanus toxoid. This innovative vaccine has a higher immunogenicity response and is T-cell dependent 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
2-Phenoxyethanol
Sodium chloride
Water For Injection

6.2 Incompatibilities
This vaccine must not be mixed with other medicinal products.

6.3 Shelf life
36 months

6.4 Special precautions for storage
Store at +2°C to +8°C (35.6°F to 46.4°F). Do not freeze.
Discard if found frozen. Keep out of reach of children.
Do not use the vaccine after the expiration date shown on the label. Opened vial should be used within 6 hours when stored under refrigeration at 2º - 8ºC (35º - 46ºF). For the multi dose vials use different syringe each time to vaccinate.

6.5 Nature and contents of container
Typbar TCV™ is presented in USP Type 1 glass vial closed with bromobutyl rubber stoppers and Pre-Filled Syringes
Single dose vial : 0.5 ml
Single dose Pre-Filled Syringe : 0.5 ml
Multi dose (5 doses) vial : 2.5 ml

6.6 Special precautions for disposal and other handling
Once opened, multi dose vials of BioE's Typhoid VI conjugate vaccine from which one or more doses of vaccine have been removed during an immunization session may be used in subsequent immunization sessions for up to a maximum of 28 days, provided that all of the following conditions are met:
- the expiry date has not passed
- the vaccines are stored under appropriate cold chain conditions
- the vaccine vial septum has not been submerged in water
- Aseptic technique has been used to withdraw all doses
- The vaccine vial monitor (VVM) (if attached) has not reached the discard point

7. Applicant
Bharat Biotech International Limited
Genome Valley, Shameerpet Mandal
Medchal district- 500078, Telangana
India.

8. Manufacturer
Bharat Biotech International Limited
Genome Valley, Shameerpet Mandal
Medchal district- 500078, Telangana
India.

9. Registration details
Zimbabwe registration number_Single dose 0.5ml vial: 2022/18.2/6229
Zimbabwe registration number_Prefilled syringe: 2022/18.2/6230
Zimbabwe registration number_5 dose vial: 2022/18.2/6231

Zimbabwe category of distribution: Prescription Preparations (P.P.)

10. Date of revision of the text
5 May 2023