SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

Brand Name: TYPBAR

Generic Name: Vi Capsular Polysaccharide Typhoid Vaccine B.P.

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

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

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:

- Traveller’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.

Method of Administration:
TYPBAR is for Intramuscular injection only. DO NOT inject intravenously.
TYPBAR in adults 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 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.

Special Precaution and Warnings 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 Reaction:
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 rare cases, allergic-type reactions (pruritus, rash, urticaria) may be observed.

Efficacy and safety information
The clinical study clearly demonstrates the Safety and Immunogenicity of the TYPBAR (Vi capsular Polysaccharide Typhoid vaccine) by inducing strong immune response to the injected antigens. Seroconversion rates on the 28th day after immunization with TYPBAR are 76.71%. The Reactogenicity profile of the Test Vaccine is similar to that of previously reported in other studies. Some of the study subjects were followed up to a period of six months for safety. Hence it can be concluded that TYPBAR Vaccine manufactured by Bharat Biotech is Safe & immunogenic to protect against typhoid infection.
Pharmaceutical Particulars:

Category: Active immunization 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.

Revision Version: 54101.02

Name and address of Manufacturer and Marketing Authorization Holder

Manufactured By:

Name of the Company: Bharat Biotech International Limited
Trading Style: Bharat Biotech International Limited
Address of the Site & Corporate Office: Genome Valley, Shameerpet Mandal, Hyderabad, Andhra Pradesh, INDIA – 500078.

Marketed By: Biovalys Co., Ltd. Bangkok, Thailand.

MARKETING AUTHORIZATION NUMBERS

1C 7/58(B)

DATE OF AUTHORIZATION

February 26, 2015

DATE OF REVISION OF THE TEXT

May 9, 2018