Summary of Product Characteristics (SmPC)

1. Name of the Medicinal Product:

Brand Name:

TYPBAR®

Generic Name:

Typhoid Polysaccharide Vaccine BP

2. Qualitative and Quantitative Composition:

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.

Each dose of 0.5 mL contains:

Purified Vi Capsular Polysaccharide of *Salmonella typhi Ty2*…… 25 µg

Phenol BP ……....NMT 0.25% w/v

Phosphate Buffered Saline…….....q.s. to 0.5 mL

3. Pharmaceutical Form:

Liquid for injection.

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:

- Travellers to high endemic areas.
- Household contacts of carriers.
- Healthcare personnel.
- Police, armed forces and other such regimented personnel.

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4.2 Dosage and method of administration:

Posology:

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.

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.

4.3 Contraindications:

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

4.4 Special warnings 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

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patients with immunodeficiency, an adequate response may not be achieved.

4.5 Interaction with other medicinal product and other forms of interaction:

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

4.6 Pregnancy and lactation:

The effect of the **TYPBAR®** on foetal development or reproduction capacity has not been evaluated. **TYPBAR®** should be given to a pregnant woman only if clearly needed.

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

4.7 Effect on ability to drive and use machine:

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, and urticaria) may be observed.

4.9 Over dose:

Not applicable.

5. Pharmacological Properties:

5.1 Pharmacodynamic properties:

Not applicable.

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5.2 Pharmacokinetic properties:

Not applicable

5.3 Preclinical safety data

Not applicable

6. Pharmaceutical Particulars

6.1 List of excipients:

Each dose of 0.5 mL contains:

Phenol BP …..…… NMT 0.25% w/v

Phosphate Buffered Saline……...q.s. to 0.5 mL

6.2 Incompatibilities:

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

6.3 Shelf life:

Vial Presentation: 3 years from the date of manufacture.

PFS Presentation: 3 years from the date of manufacture.

6.4 Special precautions for storage:

Store at 2°C to 8°C.

Do not freeze. Discard if frozen. Keep out of reach of children.

6.5 Nature and content of the container:

TYPBAR® is presented in USP type I glass vial and PFS

Single dose	: 0.5mL
Multi-dose	: 2.5mL
Multi-dose	: 5.0mL

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Single dose PFS : 0.5mL

6.6 Special precautions for disposal:

Not Applicable.

Instructions for use / handling:

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.

Additional information:

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.

7.0 Marketing Authorisation Holder:

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