TYPHOID POLYSACCHARIDE VACCINE I.P.
VacTyph®

Summary of product characteristics as per Annexure C

1. NAME OF THE MEDICINAL PRODUCT

- Typhoid Polysaccharide Vaccine I.P.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 0.5 ml contains:

Purified Vi Capsular polysaccharide of *S. typhi*	0.025 mg
Phenol as preservative maximum	0.25 % w/v
Isotonic buffer solution	q.s.

3. PHARMACEUTICAL FORM

Drug Substance(s)

- Purified Vi Polysaccharide of *Salmonella typhi* has been developed as per WHO TRS 840 Annexure 1 and Indian Pharmacopoeia.

Drug Product

- Typhoid Polysaccharide Vaccine I.P has been developed as per WHO TRS 840 Annexure 1 and Indian Pharmacopoeia.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

VacTyph® is indicated for active immunization against typhoid fever in adults and children over 2 years of age.

4.2 Posology and method of administration

The recommended dose of VacTyph® is single dose of 0.5 ml administered intramuscularly. Do NOT administer by intravascular injection. Ensure that the vaccine does not penetrate a blood vessel.

Do NOT inject this vaccine into the gluteal area or areas where there may be a nerve trunk.

Revaccination: A single dose at 3 yearly intervals in subjects who remain at risk from typhoid fever.

VacTyph® should be given intramuscularly in the deltoid (upper arm) muscle in adults and in children in the vastus lateralis (anterolateral thigh) up to 12 years of age.

4.3 Contraindications

VacTyph® is contraindicated in patients with a history of hypersensitivity to any component of this vaccine.

Vaccination must be postponed in case of febrile or acute disease.

4.4 Special warnings and precautions for use

This vaccine provides protection against the risk of infection related to *Salmonella typhi* but gives no protection against *Salmonella paratyphi A or B* or against *non-typhoidal Salmonellae*.

Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.

Do not administer intravenously, intradermally, or subcutaneously.

Like all other vaccines, supervision and appropriate medical treatment should always be available to treat any anaphylactic reactions following immunization.

Epinephrine injection (1:1000) must be immediately available in case of an acute anaphylactic reaction or any allergic reaction occurring due to any component of the vaccine.

The vaccine should remain under medical supervision for at least 30 minutes after vaccination.

As with all injectable vaccines, VacTyph® must be administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may occur following intramuscular administration to these subjects.

As with any vaccine, vaccination with VacTyph® may not result in protection in all vaccine recipients.

The immunogenicity of VacTyph® may be reduced by immunosuppressive treatment or immunodeficiency. In such cases it is recommended to postpone vaccination until the end of the disease or treatment.

The administration of VacTyph® should be deferred if fever or acute infection is present.

The vaccine should be shaken well before use & should not be used if frozen.

4.5 Interaction with other medicinal products and other forms of interaction

For concomitant or co-administration, use different injection sites and separated syringes. VacTyph® should not be mixed with any other vaccine or medicinal product, because interaction with other vaccines or medical products have not been established.

Immunosuppressive therapies may reduce the immune response to VacTyph®. As with other intramuscular injections, use with caution in patients on anticoagulant therapy.

4.6 Special Population

Animal reproduction studies have not been conducted with VacTyph®. There is no data on the use of this vaccine in pregnant women. Therefore, the administration of the vaccine during pregnancy is not recommended. VacTyph® should be given to pregnant women only if clearly needed and following an assessment of the risks and benefits. It is not known whether this vaccine is excreted in human milk. Caution must be exercised when VacTyph® is administered to a nursing mother. Safety and effectiveness of VacTyph® has not been established in children below the age of 2 years.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

The adverse events reported with typhoid polysaccharide vaccine include the following:

- Very common (≥1/10): injection site pain, injection site erythema, injection site swelling/ edema/ induration, headache, myalgia, malaise and fatigue / asthenia
- Common (≥1/100 to <1/10): fever
- Uncommon (≥1/1000 to <1/100): injection site pruritus
- Not known (cannot be estimated from the available data): Nausea, vomiting, diarrhoea, abdominal pain, anaphylactic / anaphylactoid reactions including shock, Serum sickness disease, pruritus, rashes, urticaria, arthralgia and vasovagal syncope in response to injection.

4.9 Overdose

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMICPROPERTIES

Typhoid fever is a very common and serious bacterial disease caused by *Salmonella typhi*. Typhoid polysaccharide vaccine contains purified Vi capsular polysaccharide of *Salmonella typhi*. The vaccine is immunogenic and is T-cell independent which induces Vi antibodies that neutralize Vi antigen and hence prevents the infection. Immunity appears within 1-3 weeks after injection and lasts around 3 years

5.2 PHARMACOKINETIC PROPERTIES

Evaluation of pharmacokinetic properties is not required for vaccines.

5.3 Preclinical safety data

5.3.1 Animal Toxicology & Pharmacology:

Not applicable OR Preclinical data reveal no special hazard for humans based on conventional studies of safety and of toxicity.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Potassium dihydrogen orthophosphate
- Disodium hydrogen orthophosphate
- Sodium chloride
- Potassium chloride
- Phenol
- Sodium hydroxide
- Hydrochloric acid

6.2 Incompatibilities

This vaccine must not be mixed with other medicinal products.

6.3 Shelf life

The expiry date of the vaccine is indicated on the label and carton of the product.

6.4 Special precautions for storage

Store at 2°C to 8°C.
Do not freeze.
Keep out of reach of children.

6.5 Nature and contents of container

Nature and contents of container for Vials

2R Clear tubular Glass Vial - USP Type I with 13 mm Grey Bromo Butyl Rubber Stopper and 13 mm Aluminium Flip Off Seals.

Nature and contents of container for PFS

1.0 ml PFS USP Type I Glass Barrels with Rubber plunger Bromo Butyl

6.6 Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

7. Details of manufacturer

Zydus Lifesciences Limited
Plot Survey No. 23, 25/P, 37, 40/P, 42 to 47
Sarkhej- Bavla N.H. 8A, Opp. Ramdev Masala,
Village: Changodar, Taluka: Sanand,
Dist. Ahmedabad – 382 213

8. MARKETING AUTHORISATION NUMBER(S)

Permission No. MF-821

9. DATE OF FIRST AUTHORISATION

9th September, 2003