Summary of Product Characteristics

1. Name of the medicinal product

Vaxphoid Vaccine

2. Qualitative and quantitative composition

Each vial contains 0.5 ml Typhoid Polysaccharide Vaccine BP containing ≥ 25µg of Vi capsular polysaccharide of *Salmonella typhi* Ty2 strain.

3. Pharmaceutical form

Clear, colorless sterile solution for intramuscular use containing the Vi polysaccharide extracted from *Salmonella typhi* Ty2 strain.

4. Clinical particulars

4.1 Therapeutic indications

Vaxphoid is indicated for active immunization against typhoid fever in both adults and children two years of age or older. Selective immunization with typhoid vaccine is recommended for the following:

- Travelers to high endemic areas
- Household contact of carriers
- Healthcare personnel
- Police, Armed forces and such other regimented personnel
- Laboratory workers who work with Salmonella typhi

4.2 Posology and method of administration

Posology

A single dose of 0.5 ml is recommended for both adults and children two years of age or older.

Subjects who remain at risk of typhoid fever should be revaccinated using a single dose of vaccine with an interval of not more than 3 years.

Method of administration

Vaxphoid is for intramuscular injection only. Do not inject intravenously.

Vaxphoid should be given intramuscularly in the deltoid and children should be injected intramuscularly either in the deltoid or the vastus lateralis. It should not be injected into the gluteal areas where there may be a nerve trunk.

Vaxphoid injection should be administered with caution to subjects with thrombocytopenia or bleeding disorders since bleeding may occur following an intramuscular administration to these subjects. Following injections, film pressure should be applied to the site (without rubbing) for at least two minutes.

4.3 Contraindications

The vaccine protects against typhoid fever caused by *Salmonella typhi*. Protection is not conferred against paratyphoid fever or illness caused by non- invasive Salmonella.

Typhoid vaccine should not be administered to subject with known hypersensitivity to any component of the vaccine or to subjects having shown signs of hypersensitivity after previous Typhoid vaccine administration, or after any other vaccine containing Vi polysaccharide *Salmonella typhi* antigens.

It may be expected that in patients receiving immunosuppressive treatment or patients with immunodeficiency, an adequate response may not be achieved. The administration of Typhoid vaccine should be postponed in subjects suffering from acute severe febrile illness.

4.4 Special warnings and precautions for use

The vaccine should be shaken gently and visually inspected for any foreign particulate matter and/or variation of physical aspect prior to administration. In the event of either of the above being observed, discard the vaccine.

As with other vaccines appropriate medical treatment, epinephrine injection (1:1000) must be immediately available, should be acute anaphylactoid reaction occur due to any component of the vaccine. The vaccinee should remain under medical supervision for not less than 30 minutes after vaccination.

4.5 Interaction with other medicinal products and other forms of interaction

Not applicable

4.6 Fertility, pregnancy and lactation

Pregnancy:

The effect of typhoid vaccine on foetal development or reproduction capacity has not been evaluated. Typhoid vaccine should only be used during pregnancy when there is a high risk of infection.

Lactation:

It is not known if Typhoid vaccine is excreted in human milk. It may be administered to nursing mothers only if clearly needed.

Fertility:

No fertility data are available.

4.7 Effects on ability to drive and use machines

Not Applicable

4.8 Undesirable effects

Mild local pain, redness, induration and fever may occur during the 48 hours following injection. Paracetamol or Ibuprofen cover for 36 hours after vaccination shall decrease the intensity of side effects.

4.9 Overdose

Not applicable.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Not applicable for vaccines as immunizing doses are too less for Pharmacodynamics studies.

5.2 Pharmacokinetic properties

Evaluation of Pharmacokinetic properties is not required for vaccine.

5.3 Preclinical safety data

In the preclinical safety Data typhoid polysaccharide vaccine was found safe.

6. Pharmaceutical particulars

6.1 List of excipients

Phenol
Isotonic saline

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years from the date of manufacturer when stored at 2 – 8 °C.

6.4 Special precautions for storage

- Keep out of the reach of children.
- Store at $+2^0$C to $+8^0$C.
- Transportation should also be at $+2^0$C to $+8^0$C.
- Do not freeze. Discard vaccine if frozen.
- Protect from light.

6.5 Nature and contents of container

Various materials used for the final packing of vaccine are as follows:

i) Glass Vials:

2 ml, 13 mm clear tubular type I glass vial for single dose & 5 ml, 13 mm clear tubular type 1 glass vial for multi dose.

- **Rubber closures:**
  13 mm Grey butyl, 'Bioclean RFU' Rubber stopper.

- **Aluminium Seals:**
  13 mm flip off BE-11 aluminium seals.

ii) Sterile disposable syringe

6.6 Special precautions for disposal and other handling

No special requirements

7. Marketing authorization holder

Incepta Vaccine Ltd.

38-40, Shahid Tajuddin Sarani

Tejgaon I/A, Dhaka.

Trading as:

Incepta Vaccine Ltd.

8. Drug authorization number(s)

363-01-069

9. Date of first authorization/Renewal of authorization

14 February, 2011

10. Date of revision of the text

May, 2021