TYPHE**RIX**™

1. Name of the medicinal product

Typherix™. Vi polysaccharide typhoid vaccine.

2. Qualitative and quantitative composition

Typherix™ is a clear isotonic colourless solution containing the cell surface Vi polysaccharide extracted from *Salmonella typhi* Ty2 strain.

Typherix™ complies with WHO and European Pharmacopoeia monograph requirements for Vi polysaccharide typhoid vaccines.

Each 0.5 ml dose of vaccine contains 25 µg of the Vi polysaccharide of *Salmonella typhi*.

3. Pharmaceutical form

Solution for injection.

4. Clinical particulars

4.1 Therapeutic indications

Active immunisation against typhoid fever for adults and children older than two years of age.

4.2 Posology and method of administration

Posology

A single dose of 0.5 ml containing 25 µg of the Vi polysaccharide of *Salmonella typhi* is recommended for both children and adults.

Subjects who remain at risk of typhoid fever should be revaccinated using a single dose of vaccine every 3 years.

Method of administration

Typherix™ is for **intramuscular** injection.

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

4.3 Contra-indications

Typherix™ should not be administered to subjects with known hypersensitivity to any component of the vaccine or to subjects having shown signs of hypersensitivity after previous administration.

4.4 Special warnings and special precautions for use

As with other vaccines, the administration of **Typherix™** should be postponed in subjects suffering from acute febrile illness.

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

Typherix™ has not been evaluated in children under 2 years of age. Nevertheless, it is known that children under this age may show a suboptimal response to polysaccharide antigen vaccines. The decision to use the vaccine in this age group should be based upon the risk of exposure to disease.

As with all injectable vaccines appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic reaction following administration of the vaccine.

Typherix™ should under no circumstances be administered intravascularly.

4.5 Interaction with other medicaments and other forms of interaction

In clinical studies in adults, **Typherix™** has been administered concomitantly in opposite arms with **Havrix™ 1440 Adult** GlaxoSmithKline inactivated hepatitis A vaccine.

There was no adverse impact on either the reactogenicity or immunogenicity of the vaccines when they were administered simultaneously in opposite arms.

Although the concomitant administration of **Typherix™** and other vaccines (other than **Havrix™ 1440 Adult**) has not specifically been studied, it is anticipated that no interaction will be observed.

Different injectable vaccines should always be administered at different injection sites.

It may be expected that in patients receiving immunosuppressive treatment or patients with immunodeficiency, an adequate response may not be achieved.

4.6 Pregnancy and lactation

Adequate human data on use during pregnancy or lactation and adequate animal reproduction studies are not available.

4.7 Effects on ability to drive and use machines

The vaccine is unlikely to produce an effect on the ability to drive and use machines.

4.8 Undesirable effects

In clinical studies, in the majority of instances, redness, pain and swelling were usually reported only during the first 48 hours following immunisation. The most common reaction, pain, has been reported in approximately 7% of vaccinees.

In clinical studies, systemic reactions were also transient; the incidence of the most frequently reported symptoms, fever, headache, general aches, malaise, nausea and itching did not exceed 9%. Anaphylaxis, allergic reactions including anaphylactoid reactions and urticaria have been reported very rarely.

4.9 Overdose

Not applicable.

5. Pharmacological properties

5.1 Pharmacodynamic properties

In clinical studies, seroconversion was observed in > 95% of recipients when measured at two weeks after administration.

Immunity persists for at least 3 years.

For individuals who remain at - or who may be reexposed to - risk of typhoid fever, it is recommended that they be revaccinated using a single dose of vaccine every 3 years.

5.2 Pharmacokinetic properties

Evaluation of pharmacokinetic properties is not required for vaccines.

5.3. Preclinical safety data

Not applicable.

6. Pharmaceutical particulars

6.1 List of excipients

Sodium chloride, dibasic sodium phosphate, monobasic sodium phosphate, phenol and water for injections.

6.2 Incompatibilities

Typherix™ should not be mixed with other vaccines in the same syringe.

6.3 Shelf-life

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

6.4 Special precautions for storage

Store at 2°C to 8°C. Protect from light.

Do not freeze.

6.5 Nature and contents of container

Typherix™ is presented as a clear, colourless, liquid vaccine in a glass prefilled syringe made of neutral glass type 1 which complies with European Pharmacopoeia requirements.

6.6 Instructions for use/handling

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

Shake before use.

For further information, please contact manufacturer.

Typherix™ and **Havrix™** are trademarks.

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