



Package Leaflet: Information for the User
Typherix®, solution for injection in a pre-filled syringe
Typhoid Polysaccharide vaccine



474664



Read all of this leaflet carefully before you start receiving this vaccine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This vaccine has been prescribed for you only. Do not pass it on to others.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- 1 What Typherix is and what it is used for
- 2 What you need to know before you receive Typherix
- 3 How Typherix is given
- 4 Possible side effects
- 5 How to store Typherix
- 6 Contents of the pack and other information

1 What Typherix is and what it is used for

Typherix is a vaccine which helps prevent typhoid fever, an infectious illness caused by a type of bacteria called *Salmonella typhi*.

This vaccine can be given to both adults and children aged 2 years and over. In this leaflet, any reference to 'you' can also mean 'your child'.

How Typherix works

Typherix contains a small part of the bacterium which causes typhoid fever. This is not infectious and cannot make you ill.

- When you are given the vaccine it will trigger the body's immune system to prepare itself to protect against typhoid fever in the future.
- Typherix will only prevent disease caused by the bacterium *Salmonella typhi* and not against salmonella bacteria that can cause food poisoning or gastroenteritis.

Typhoid fever is an infectious illness caused by a bacterium, *Salmonella typhi*. It is caused and spread by eating or drinking contaminated food or water. Since the bacterium is present in the bowel movement (motion), the infection can occur in any country, but it more commonly occurs in places or countries with poor personal or public hygiene.

The main signs of the illness include headache, pains in the stomach, constipation or diarrhoea and a fever that may last for one or two weeks. Patients normally get better after about four weeks, but relapses can occur.

2 What you need to know before you receive Typherix

Typherix should not be given

- if you are allergic to Typherix or any of the other ingredients of this vaccine (listed in section 6)
- if you have a high temperature (fever)

Typherix should not be given if the above applies to you. If you are not sure, talk to your doctor or pharmacist before having Typherix.

Warnings and precautions

Talk to your doctor or pharmacist before you are given Typherix

- if you have any bleeding disorders or suffer from excessive bleeding. Since bleeding may occur while being vaccinated, firm pressure should be applied to the injection site for at least two minutes after the injection.
- if you have a poor immune system or you are taking medicines such as steroid tablets that may affect your immune system.

If you are not sure any of the above apply to you, talk to your doctor or pharmacist before having Typherix.

Fainting can occur (mostly in adolescents) following, or even before, any needle injection. Therefore tell the doctor or nurse if you/your child fainted with a previous injection.

Other medicines and Typherix

Tell your doctor or pharmacist if you are taking, have recently taken, might take any other medicines, including other vaccines. Typherix can be given at the same time as some other vaccines. Your doctor will ensure that the vaccines are injected separately and into different parts of the body.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before you are given this vaccine.

Driving and using machines

Typherix may affect your ability to drive or use machines. Do not drive or use machines if you are feeling unwell.

3 How Typherix is given

How your vaccine is given

Typherix will be given:

- as an injection into the muscle of the upper arm
- at least two weeks before the risk of being exposed to typhoid fever

How much is given

- Both adults and children above 2 years of age will receive a 0.5 ml dose.
- If you remain at risk of catching typhoid fever, your doctor may recommend a second dose of Typherix within 3 years of the first dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4 Possible side effects

Like all vaccines, this vaccine can cause side effects although not everybody gets them. The following side effects may happen with this vaccine:

Allergic reactions (these may occur with up to 1 in 10,000 doses of the vaccine)
If you have an allergic reaction, see your doctor straight away. The signs may include:

- your face swelling
- low blood pressure
- difficulty breathing
- your skin going blue
- loss of consciousness

The signs usually start very soon after the injection has been given to you. See a doctor straight away if they happen after leaving the clinic.

Other side effects include:

Common (these may occur with up to 1 in 10 doses of the vaccine)

- pain, redness and swelling at the injection site
- a high temperature (fever)
- headache
- general aches and pains
- feeling generally unwell
- feeling sick
- itching

Very Rare (these may occur with up to 1 in 10,000 doses of the vaccine)

- severe rashes (urticaria)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Typherix

- Keep this vaccine out of the sight and reach of children
- Store in a refrigerator (2°C - 8°C)
- Do not freeze
- Protect from light
- Do not use this vaccine after the expiry date which is stated on the label and the carton. The expiry date refers to the last day of that month
- Store in the original package with this leaflet
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6 Contents of the pack and other information

What Typherix contains

- The active substance is 25 micrograms of the Vi polysaccharide antigen, a part of the *Salmonella typhi* (Ty2 strain) bacterium that causes typhoid fever.
- The other ingredients are sodium chloride, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate, phenol and water for injections.

What Typherix looks like and contents of the pack

- Typherix is a clear colourless solution.
- Typherix is available as 0.5 ml pre-filled syringes and is available in packs of 1, 10, 50 or 100, however not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
GlaxoSmithKline (Ireland) Ltd., 12 Riverwalk, Citywest Business Campus, Dublin 24

Manufacturer:
GlaxoSmithKline Biologicals s.a., Rue de l'Institut 89, B-1330 Rixensart, Belgium

This leaflet was last revised in July 2015

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The following information is intended for medical or healthcare professional only:

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