

Patient Information Leaflet on 'Typherix'

25 micrograms/0.5 ml

Vi polysaccharide typhoid vaccine

Solution for injection

This leaflet tells you about typhoid vaccine. Please read it carefully. If there is anything you do not understand, or if you want to know more about this vaccine ask your doctor, nurse or pharmacist (chemist). Please keep this vaccine out of the reach of children. Please keep this leaflet, you may want to read it again.

What is in typhoid vaccine?

The name of your vaccine is 'Typherix'. This vaccine contains the cell surface Vi polysaccharide extracted from *Salmonella typhi* Ty2 strain as a single 0.5 ml dose in a prefilled syringe. Each 0.5 ml of the vaccine contains 25 mcg of the Vi polysaccharide of *Salmonella typhi*. The vaccine also contains inactive ingredients. These are sodium chloride, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate, phenol and water for injections. The vaccine is available in packs of one and 10 glass prefilled syringes.

Who makes 'Typherix' vaccine?

The Product Licence holder is SmithKline Beecham plc, trading as GlaxoSmithKline UK, Stockley Park West, Uxbridge, Middlesex, UB11 1BT. The Product Licence number is 10592/0126. The vaccine is manufactured by GlaxoSmithKline Biologicals s.a. 89 rue de l'Institut, B-1330 Rixensart, Belgium.

What is 'Typherix' and how does it work?

'Typherix' Vaccine is a clear, colourless solution which contains a part (the cell surface Vi polysaccharide) of the bacterium *Salmonella typhi* Ty2 strain which cause typhoid fever. When you are given the vaccine your body will make antibodies (your body's natural defence system) against the *Salmonella typhi* bacterium. This will protect you against typhoid fever.

Before having this vaccine

If you answer YES to any of the following questions, tell your doctor or nurse. You may not be able to have the vaccine or it may have to be delayed.

- Do you have a fever or an infection?
- Do you think you may be allergic to 'Typherix' or any of the ingredients listed?
- Do you have a poor immune system or are you taking medicines (such as steroid tablets) that may affect your immune system?
- Is the person to be vaccinated under two years of age?
- Are you pregnant or do you think you may be?
- Are you breast-feeding?
- Do you have any bleeding disorders, such as thrombocytopenia?

Having the vaccine

'Typherix' is injected into the muscle in your upper arm. The vaccine is suitable for those aged two years and older. Your doctor will give you instructions on when to receive 'Typherix' vaccine. One injection of the vaccine should protect you from infection for at least three years.

After having the vaccine

What unwanted effects might you have?

You may have mild soreness, redness or swelling at the site of the injection. This should last only a few days.

You may feel unwell or have a fever or headache or mild itching. Some people can, very rarely, have an allergic reaction to the vaccine. You may be asked to stay in the surgery or vaccination area for a short time after the vaccination, to check that you do not have an immediate allergic reaction. Tell the doctor or nurse if you get a rash, have tightness in the throat or shortness of breath or any other unwanted effects.

Storage of this vaccine

This vaccine should be stored in a refrigerator until it is given to you. The doctor or nurse should check that the expiry date on the label has not passed. The vaccine must not be frozen.

If your doctor has given you a prescription for 'Typherix' to collect from your pharmacist (chemist) instead of giving it to you straight away, you must store the vaccine carefully. Keep it in your fridge (between 2°C and 8°C) in the original package in order to protect from light.

Disease information on typhoid fever

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 faeces, 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. 'Typherix' will only prevent disease caused by the bacterium *Salmonella typhi* and not against salmonella bacteria that can cause food poisoning or gastroenteritis.

Leaflet prepared in September 2002

'Typherix' and the GSK logo are trade marks of the GlaxoSmithKline Group of Companies

©2002 GlaxoSmithKline Group of Companies

 GlaxoSmithKline