

TYPHERIX[®]

(Typhoid Vaccine)

CONSUMER MEDICINE INFORMATION LEAFLET

What is in this leaflet

This leaflet answers some of the common questions about TYPHERIX vaccine. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines and vaccines have risks and benefits. Your doctor has weighed the possible risks of you or your child having TYPHERIX against the expected benefits.

If you have any concerns about receiving TYPHERIX talk to your doctor, nurse or pharmacist.

Keep this leaflet with this vaccine. You may need to read it again.

What TYPHERIX is used for

TYPHERIX is a vaccine used to prevent typhoid fever in adults and children aged two and above. The vaccine works by causing the body to produce its own protection (antibodies) against this disease.

Typhoid fever is caused by bacteria called *Salmonella typhi*. Typhoid fever can cause persistent high fever which may last for 10-14 days, tiredness, headache, stomach pains and a rose coloured rash. In severe cases, it may cause tears and bleeding in the intestines. The death rate can be as high as 12% if left untreated.

Some antibiotics can be used to treat typhoid fever. However, vaccination is the best way to protect against infection.

Before receiving TYPHERIX

When you must not have TYPHERIX

Tell your doctor if:

- you have/ your child has had an allergic reaction to TYPHERIX, or any ingredient contained in this vaccine. The ingredients are listed at the end of this leaflet. Signs of an allergic reaction may include an itchy skin rash, shortness of breath and swelling of the face or tongue.
- you have/ your child has had an allergic reaction to any other typhoid vaccine
- you have/ your child has a severe infection with a high temperature. A minor infection such as a cold should not be a problem, but talk to your doctor about this before being vaccinated
- the expiry date printed on the pack has passed
- the packaging is torn or shows signs of tampering

If you are not sure whether TYPHERIX should be given, talk to your doctor or nurse.

Before receiving TYPHERIX

Tell your doctor if:

- you are or think you may be pregnant or if you intend to become pregnant. Your doctor will discuss with you the possible risks and benefits of receiving TYPHERIX during pregnancy
- you are breast-feeding. It is not known if TYPHERIX passes into breast milk, however the vaccine is not expected to cause problems for breast-fed babies
- you have/ your child has any medical conditions, such as:
 - an immune deficiency condition (eg. HIV positive)
 - a bleeding disorder
- you have/ your child has allergies to any other medicines or substances, such as dyes, foods or preservatives

- you have/ your child has received another vaccine recently, or are taking any prescription or OTC (over-the-counter) medicines. In particular, mention if you are taking medicines which suppress the immune system, such as steroids or cyclosporin.

Some vaccines may be affected by other vaccines or medicines. Your doctor or pharmacist will be able to tell you what to do if TYPHERIX is to be given with another vaccine or medicine.

Use in children

TYPHERIX can be used in children two years of age and older.

How TYPHERIX is given

The doctor or nurse will give TYPHERIX as an injection. If you have any concerns about how this vaccine is to be given, talk to your doctor or pharmacist.

TYPHERIX will be injected into the upper arm muscle.

The vaccine should never be given intravenously.

How much is given

For adults and children the TYPHERIX dose is 0.5 mL.

When is it given

Only one injection of TYPHERIX is generally needed. TYPHERIX should be given at least two weeks prior to travelling to an area where you may be at risk of coming into contact with typhoid fever. A single dose of TYPHERIX should be given every three years to those people who remain at risk of typhoid fever.

Your doctor will advise on the possible need for future booster dosing.

While you are using TYPHERIX

Things to be careful of:

Be careful driving or operating machinery until you know how TYPHERIX affects you. TYPHERIX should not normally interfere with your ability to drive a car or operate machinery. But in some people vaccination can cause dizziness or lightheadedness. Make sure you know how you react to TYPHERIX before you drive a car or operate machinery, or do anything that could be dangerous if you feel dizzy or lightheaded.

Side-Effects

Tell your doctor, nurse or pharmacist as soon as possible if you or your child do not feel well during or after a dose of TYPHERIX.

TYPHERIX helps protect most people from typhoid fever, but it may have unwanted side effects in a few people. All medicines and vaccines can have side effects. Most of the time they are not serious; however, sometimes they can be. Some side effects may need medical treatment.

Most unwanted effects with TYPHERIX are mild and usually clear up within a few days. Ask your doctor or pharmacist to answer any questions you may have.

Mild events that have been reported after TYPHERIX vaccination

Tell your doctor if you notice any of the following that are troublesome or ongoing:

- soreness, redness, swelling, itching around the injection site
- headache, fatigue, general aches, feeling sick, nausea.

As with all vaccines given by injection there is a very small risk of serious allergic reaction. This may occur days to weeks after vaccination. Contact your doctor immediately or go to the Accident and Emergency department of your nearest hospital if any of the following happens:

- swelling of limbs, face, eyes, inside of nose, mouth or throat
- shortness of breath, breathing or swallowing difficulties
- hives, itching (especially of the hands or feet), reddening of skin (especially around the ears), or severe skin reactions.

Other side effects not listed above, can also occur during or soon after a dose of TYPHERIX. **Check with your doctor, nurse or pharmacist if you or your child have any other effects.**

Do not be alarmed by this list of possible side effects. You or your child may not experience any.

Storage

TYPHERIX is usually stored at the doctor's clinic or surgery, or at the pharmacy. But if you need to store TYPHERIX always:

- Keep TYPHERIX in the refrigerator stored between +2°C and +8°C. **THE PACK SHOULD NEVER BE FROZEN. FREEZING DESTROYS THE VACCINE.**
- Keep the vaccine out of the reach of children.
- Keep TYPHERIX in the original pack until it is time for it to be given.

Ask your pharmacist what to do with any left over TYPHERIX that has expired or has not been used.

Product Description

What it looks like

TYPHERIX comes in prefilled syringes. It is a clear, colourless liquid.

Ingredients

The active ingredient of TYPHERIX is a surface protein of the *Salmonella typhi* bacteria. The vaccine is not infectious, and will not give you typhoid.

Inactive ingredients in the vaccine are: sodium chloride, phosphate buffer (sodium phosphate, disodium phosphate), phenol and water for injections.

TYPHERIX is made without any human blood or blood products, or any other substances of human origin.

Further Information

TYPHERIX is only available if prescribed by a doctor.

TYPHERIX is available as:
Prefilled syringes in packs of 1

Manufacturer

SmithKline Beecham Biologicals s.a.
Rue de l'Institut 89,
B-1330 Rixensart,
Belgium

Sponsor

GlaxoSmithKline NZ Ltd

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