

VIVAXIM[®]

Salmonella typhi Vi polysaccharide and inactivated hepatitis A virus antigen vaccine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about VIVAXIM[®]

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines, including vaccines, have risks and benefits. Your doctor has weighed the risks of you having VIVAXIM[®] against the benefits they expect it will have for you.

If you have any concerns about this vaccine, ask your doctor, nurse or pharmacist.

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

What VIVAXIM[®] is used for

VIVAXIM[®] is a vaccine used to help prevent Typhoid fever and Hepatitis A disease in adults over the age of 16 years who are at risk of these diseases.

How it works

VIVAXIM[®] works by causing your body to produce its own protection against typhoid fever and hepatitis A infection. It does this by making substances called antibodies in the blood, which fight the typhoid bacteria and hepatitis A viruses. If a vaccinated person comes into contact with the typhoid or hepatitis A organisms, the body is usually ready to destroy them.

Your body usually takes two weeks after vaccination to develop protection against typhoid fever and hepatitis A infection.

Initial protection is provided by one dose of VIVAXIM[®]. For long-term protection against hepatitis A virus a booster vaccination with an inactivated hepatitis A vaccine will be required 6 to 36 months after vaccination with VIVAXIM[®]. The body does not develop long-term protection against typhoid fever and repeat vaccinations are required to maintain protection.

Most people will produce enough antibodies against typhoid fever and hepatitis A infection. However, as with all vaccines, 100% protection cannot be guaranteed.

The vaccine will not give you Typhoid fever or hepatitis A infection.

The chance of a severe reaction from VIVAXIM[®] is very small, but the risks from not being vaccinated against Typhoid fever or Hepatitis A infection may be very serious.

Before you are given VIVAXIM[®]

When you must not be given it

- You have had a severe reaction to a previous injection of this vaccine.

Do not have VIVAXIM[®] if you have an allergy to:

- VIVAXIM[®] or any of the ingredients listed at the end of this leaflet

Symptoms of an allergic reaction may include:

- Shortness of breath, wheezing or difficulty breathing
- Swelling of the face, lips, tongue or other parts of the body
- Skin rash, itching or hives

Do not have VIVAXIM[®] if you have, a fever or acute illness.
Minor infections are not a reason to delay vaccination.

Do not have VIVAXIM[®] if you have had a severe reaction to a previous injection of this vaccine.

Do not have VIVAXIM[®] if you are pregnant or intend to become pregnant.

VIVAXIM[®] is not recommended for use during pregnancy.

Do not give VIVAXIM[®] to an adult or child under 16 years.
The safety and effectiveness of VIVAXIM[®] in adults and children under 16 years have not yet been established.

Do not have VIVAXIM[®] after the expiry date printed on the pack.

Do not have VIVAXIM[®] if the packaging is torn or shows signs of tampering.

Talk to your doctor or pharmacist if you are not sure whether you should have VIVAXIM[®].

Before you are given it

Tell your doctor if you have reacted to previous vaccination with any of the following:

- Life-threatening allergic reaction
- Difficulty breathing
- Swelling of the throat
- Fainting or collapse

- **Shock-like state or being unresponsive for a long period of time**
- **Fits or convulsions**
- **High temperature (greater than 40°C)**
- **Severe skin reaction at the injection site, including severe bruising**

Tell your doctor if you have an infection or high temperature.

Your doctor may decide to delay vaccination until the illness has passed. A mild illness, such as a cold, is not usually a reason to delay vaccination.

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- **Lowered immunity due to diseases such as some blood disorders, malaria, kidney disease requiring dialysis, HIV/AIDS or cancer**
- **Lowered immunity due to treatment with medicines such as corticosteroids, cyclosporin or other medicines used to treat cancer (including radiation therapy)**
- **Leukaemia or any other cancers of the blood, bone marrow or lymph system**

If you have lowered immunity then the vaccine may not work as well as it would in healthy individuals.

Tell your doctor if you have allergies to:

- **Any other medicines**
- **Any other substances, such as foods, preservatives or dyes**
- **Neomycin**

Tell your doctor if you are pregnant or intend to become pregnant.

VIVAXIM® is not recommended for use during pregnancy. If there is a need to consider VIVAXIM® during your pregnancy, your doctor will discuss with you the benefits and risks of having it.

Tell your doctor if you are breast-feeding.

Your doctor will discuss the possible risks and benefits of having VIVAXIM® during breastfeeding.

Taking other medicines

As VIVAXIM does not contain any live bacteria or viruses, it can generally be given at the same time as other inactivated vaccines, but at a different injection site.

Other medicines should be taken as usual after the vaccination.

VIVAXIM® can be given at the same time as yellow fever vaccine at different injection sites.

How VIVAXIM® is given

VIVAXIM® is given as a slow injection into your upper arm muscle by a doctor or nurse.

VIVAXIM® should not be injected directly into the veins or into the buttocks.

How much is given

The dose is one millilitre of the mixed vaccine.

When it is given

VIVAXIM® should be given 14 days before you are exposed to risk of both typhoid fever and hepatitis A. For long term protection against infection with hepatitis A virus you should obtain a booster dose of AVAXIM™ (hepatitis A vaccine) 6-36 months after your dose of VIVAXIM®. You should be revaccinated against Typhoid fever, every 3 years.

After having VIVAXIM®

Things you must do

- **Keep an updated record of your vaccinations.**
- **Attend any other appointments made by your doctor or nurse.**
- **Report any side effects to your doctor.**

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well after having VIVAXIM®

VIVAXIM® may have unwanted side effects in a few people. All medicines, including vaccines, can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- **Local reaction around the injection site such as redness, pain, swelling or hardness**
- **Headaches**
- **Generally feeling unwell**
- **Soreness, aching muscles, muscle tenderness or weakness (not caused by exercise)**
- **Nausea or diarrhoea**
- **Fever**

These are the more common side effects of VIVAXIM®. Mostly these are mild and short-lived.

Less common side effects include itchiness of the skin, dizziness and a rash. Very rarely some patients experience vomiting, abdominal pain and increased liver enzyme.

Tell your doctor immediately if you notice any of the following:

- **Abscess at the injection site**
- **Unusual bleeding, bruising or purple spots on the skin**
- **Skin rash, itchy spots or red lumps on the skin**
- **Painful, swollen joints**
- **Swelling of the glands in the neck, armpit or groin**
- **Itchiness, hives or rash over the body**

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- **Sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips,**

tongue or other parts of the body

- **Pinkish, itchy swellings on the skin, also called hives or nettle rash, shortness of breath, wheezing or trouble breathing**

These are very serious side effects. You may need urgent medical attention or hospitalisation.

All of these side effects are very rare.

Other side effects not listed above may occur in some patients. **Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Storing VIVAXIM®

VIVAXIM® is usually stored in the doctor's surgery or clinic, or at the pharmacy. However, if you need to store VIVAXIM®:

- **Keep it where children cannot reach it.**
- **Keep VIVAXIM® in the original pack until it is time for it to be given.**
- **Keep it in the refrigerator, between 2°C and 8°C. Do not freeze VIVAXIM®.**

Freezing destroys the vaccine.

Product description

What it looks like

VIVAXIM® is a combination vaccine contained in a dual chamber syringe. One chamber contains the hepatitis A vaccine, which appears as a white suspension, the other the typhoid vaccine, which appears as a clear liquid. The two vaccine components become mixed together when the plunger is depressed.

Ingredients

Active ingredients:

VIVAXIM

- 0.025 mg Purified *Salmonella typhi* (Ty 2 Strain) Vi Polysaccharide.
- 160 ELISA units hepatitis A virus antigen.

Other ingredients:

- Sodium chloride
- Sodium phosphate – dibasic dihydrate
- Sodium phosphate – monobasic
- Water for injections
- Aluminium hydroxide
- Phenoxyethanol
- Formaldehyde
- Medium 199 (Hanks)
- Polysorbate 80
- Neomycin (trace)
- Bovine Serum Albumin (trace)

The hepatitis A virus that this vaccine contains was grown in a cell line derived from human embryonic lung in the 1960s.

The manufacture of this product includes exposure to bovine derived materials. No evidence exists that any case of vCJD (considered to be the human form of bovine spongiform encephalopathy) has resulted from the administration of any vaccine product.

Manufacturer:

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