

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 aged 16 years and older 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 virus. 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-lasting protection against hepatitis A virus a booster vaccination with a 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 give Vivaxim to persons younger than 16 years. The safety and effectiveness of Vivaxim in persons 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 ever had a serious allergic reaction to a vaccine.

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.

Having 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.

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

Other medicines should be taken as usual after the vaccination.

How VIVAXIM is given

Vivaxim is given as a slow injection into the muscle of your upper arm.

Vivaxim should not be injected 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 may be exposed to the typhoid fever and hepatitis A. For long term protection against infection with hepatitis A virus you should obtain a booster dose of hepatitis A vaccine 6-36 months after your initial dose of Vivaxim. If you are at ongoing risk of infection with typhoid fever, 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
- Fainting.

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 fainting, vomiting, abdominal pain and increased liver enzymes.

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

Freezing destroys the vaccine.

Product description

What it looks like and contents of the pack

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 chamber contains the typhoid vaccine, which appears as a clear liquid. The two

vaccine components become mixed together when the plunger is depressed.

Ingredients

Active ingredients:

- 25 micrograms Salmonella typhi Vi Polysaccharide
- 160 antigen units hepatitis A virus antigen.

Other ingredients:

- Sodium chloride
- Dibasic sodium phosphate dihydrate
- Monobasic sodium phosphate dihydrate
- Water for injections
- Aluminium hydroxide hydrate
- Phenoxyethanol
- Formaldehyde
- Medium 199 (Hanks) (including phenylalanine)
- 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.

Name and address of the sponsor

Australia:

sanofi-aventis australia pty ltd

12 - 24 Talavera Road

Macquarie Park NSW 2113

Australia

Tel: 1800 818 806

New Zealand:

sanofi-aventis new zealand limited

Level 8

56 Cawley St

Ellerslie

Auckland

New Zealand

Tel: 0800 283 684

AUST R number

AUST R 82745

Date of preparation

05 March 2020

vivaxim-ccdsv9-cmiv4-05mar20