

Patient Information Leaflet

ViATIM®

Suspension and solution for injection in a pre-filled dual chamber syringe

Hepatitis A (inactivated, adsorbed) and Typhoid polysaccharide vaccine.

Read all of this leaflet carefully before you receive this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others.

In this leaflet:

1. What ViATIM® is and what it is used for
2. Before ViATIM® is given to you
3. Having the vaccine
4. Possible side effects of ViATIM®
5. Storing ViATIM®

The full name of your medicine is ViATIM®, Suspension and solution for injection in a pre-filled dual chamber syringe. Hepatitis A (inactivated, adsorbed) and Typhoid polysaccharide vaccine.

- Each 1 millilitre dose of ViATIM® contains the following active ingredients:
- 25 micrograms (a very small amount) of the Vi polysaccharide antigen (a part of the *Salmonella typhi* bacterium which causes typhoid fever)
 - 160 antigen units (these are units specified by the manufacturer) of inactivated hepatitis A virus. The purified virus has been treated with a chemical called formaldehyde to prevent it from causing hepatitis A infection. The hepatitis A virus has been attached to 0.3 milligram (a very small amount) of aluminium hydroxide to increase its effectiveness.
- ViATIM® may also contain small amounts of neomycin, which is an antibiotic.

There are also some inactive ingredients. These are sodium chloride, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate, 2-phenoxyethanol solution, formaldehyde, Medium 199 Hanks (a mixture of aminoacids, mineral salts, vitamins and other components) supplemented with polysorbate 80, and Water for Injections.

The company licensed to sell ViATIM® in the UK and Ireland is Sanofi Pasteur MSD Limited. Their address is Mallards Reach, Bridge Avenue, Maidenhead, Berkshire, SL6 1QP in the UK, and Belgard Road, Tallaght, Dublin 24 in Ireland.

ViATIM® is made by Sanofi Pasteur S.A. at Parc Industriel d'Incarville, 27100 Val de Reuil, France and Campus Mérieux, 1541 avenue Marcel Mérieux, 69280 Marcy l'Étoile, Lyon, France.

1. WHAT VIATIM® IS AND WHAT IT IS USED FOR?

The pack contains a pre-filled dual chamber syringe that contains 0.5 millilitre of purified Vi polysaccharide typhoid vaccine in one chamber and 0.5 millilitre of inactivated hepatitis A vaccine in the other chamber. The two vaccines are mixed in the syringe just before injection to give 1 millilitre of the combined vaccine – this is one dose.

ViATIM® is one of a general group of medicines called vaccines, which are used to protect you against infectious diseases. This vaccine helps to protect against typhoid fever and against hepatitis A infection.

Typhoid fever is an infectious disease that may be caught from food and drink that contain the bacteria (called *Salmonella enterica*, subtype *typhi*) that cause the illness. It is a serious infection that may be fatal if not treated promptly. Hepatitis A infection is due to a virus that attacks the liver. It may be caught from food or drink that contain the virus. Symptoms include jaundice and feeling generally unwell. When you are given an injection of ViATIM®, your body's natural defences will produce protection against typhoid fever and hepatitis A infection. However, it usually takes about 14 days after the injection before you will be protected.

ViATIM® will not protect against other viruses known to infect the liver (such as hepatitis B, hepatitis C or hepatitis E viruses). Also, if you are already infected with hepatitis A virus (in the incubation period) when you are given ViATIM®, the vaccination may not work properly.

ViATIM® will not protect you against disease caused by *Salmonella* bacteria other than the particular type that causes typhoid.

The vaccine cannot cause the infections against which it protects. Remember that no vaccine can provide complete life-long protection in all people vaccinated. Section 3 of this leaflet explains when boosting doses should be given.

virus as you would otherwise but it is likely that you will still be protected against infection.

Other medicines should be taken as usual after the vaccination.

3. HAVING THE VACCINE

The vaccination should be given by staff who are trained in the use of vaccines and who are equipped to deal with any uncommon severe allergic reaction to the injection.

ViATIM® is given as an injection of one millilitre into a muscle in the upper part of your arm. Your doctor or nurse will avoid giving you the injection either into the skin or into a blood vessel. ViATIM® should not be given into your buttock.

If you suffer from haemophilia (a condition where you bruise or bleed easily) or any other condition which means you should not receive an injection into the muscle, you may be given the injection under the skin. This may make it more likely that you will get a reaction in the area where the vaccine is given.

ViATIM® will start to protect you against hepatitis A from about 14 days after you have the first dose. You will need a second dose (booster) injection of inactivated hepatitis A vaccine to give you protection against hepatitis A for at least 10 years after the booster. The second dose is usually given between 6 and 12 months after the first dose but can be given up to 36 months later. ViATIM® can be given to you to boost your immunity to hepatitis A if you have already received a first dose of inactivated hepatitis A vaccine 6 to 36 months ago, provided that you also require protection against typhoid fever.

ViATIM® will start to protect you against typhoid fever from about 14 days after having the injection and protection may last for about 3 years. If, after 3 years, you carry on being at risk from catching typhoid fever, you should arrange to receive another injection of purified Vi polysaccharide typhoid vaccine.

4. POSSIBLE SIDE EFFECTS OF VIATIM®

Like all medicines and vaccines, ViATIM® can have side effects.

Serious allergic reactions are always a rare possibility after receiving a vaccine. These reactions may include difficulty in breathing, blue discolouration of the tongue or lips, low blood pressure (causing dizziness) and collapse. When these signs or symptoms occur they usually develop very quickly after the injection is given and while the person affected is still in the clinic or doctor's surgery. If any of these symptoms occur after leaving the place

where your injection was given, you must consult a doctor IMMEDIATELY.

Very common reactions (reported by more than 1 in 10 people) were pain, redness, swelling and hardness in the area where the vaccine was injected, headache, feeling weak, feeling generally unwell and aching muscles. Pain sometimes lasted for three days or more. Severe pain or swelling at the injection site was reported by less than one in ten but more than one in a hundred people.

Common reactions (reported by less than 1 in 10 but more than 1 in a 100 people) were:

- feeling sick
 - diarrhoea
 - aching in the joints
 - fever (a high temperature)
- Uncommon reactions (reported by less than 1 in a 100 but more than 1 in a 1000 people) were:
- itchiness of the skin
 - a rash
 - dizziness

Possible rare reactions (reported by less than 1 in a 1000 but more than 1 in 10,000 people) are:

- being sick and stomach pains

Possible very rare reactions (reported by less than 1 in 10,000 people) are:

- allergic reactions with swelling of the face and neck
- allergic reactions with joint pains and a general feeling of being unwell
- asthma attacks in people who get asthma
- pins and needles
- changes in blood tests that measure how the liver is working

If you notice any other effects after the vaccination that are not mentioned here, tell your doctor or nurse.

5. STORING VIATIM®

The vaccine will normally be stored by the clinic or doctor's surgery. However, if you have been asked to collect the vaccine from a pharmacist (chemist) and to store it until the doctor or nurse can give it to you, the vaccine must be stored in a refrigerator at between 2°C and 8°C (making sure that it does not freeze) so that it keeps its effectiveness.

The liquids in the two compartments will be mixed in the syringe just before the injection is given to you. Once mixed, your doctor or nurse will shake the syringe and check that the liquid is a white suspension and that there are no large particles in it.

2. BEFORE VIATIM® IS GIVEN TO YOU

ViATIM® is only for people 16 years of age or older. To make sure that ViATIM® is suitable for you, it is important to tell your doctor or nurse if any of the points below apply to you. If there is anything you do not understand, ask your doctor or nurse to explain.

ViATIM® should not be given to you if you:

- have ever had an allergic reaction to any of the ingredients contained in ViATIM®
- you are allergic to neomycin (an antibiotic which may be present in the vaccine in small amounts).
- have an infection with a high temperature. Your vaccination may need to be delayed until you have recovered.

ViATIM® may or may not be suitable for you if the answer to any of the following questions is yes. Tell your doctor or nurse if any of the following apply to you or if you are not sure:

- do you have a poor immune response because you have had, or are having a course of treatment such as corticosteroids, cytotoxic drugs or radiotherapy? Your doctor or nurse may want to wait until the course of treatment has finished.
- do you have problems with your immune system due to AIDS or have you had a positive test for human immunodeficiency virus (HIV)? You may be given ViATIM®, but the vaccine may not protect you as well as it protects people with normal immune systems.

Pregnancy and breast-feeding

Tell your doctor or nurse if you are pregnant, think you may be pregnant, or are breast-feeding a child. Your doctor or nurse will decide if you should be vaccinated now or wait.

Driving and using machines

Dizziness has been reported in some people (less than 1 in 10 but more than 1 in 100) after receiving ViATIM®, so care should be taken when driving or using machines.

Taking other medicines or having other vaccines

As ViATIM® does not contain any live bacteria or viruses, it can generally be given at the same time as other vaccines, but at a different injection site. ViATIM® may be given at the same time as yellow fever vaccine, but at a different injection site.

If you need an injection of immunoglobulins (antibodies obtained from blood donors), this can be given at the same time or within a few weeks of having ViATIM®. You may not produce as much antibody to the hepatitis A

The vaccine should not be used after the 'Expiry' date on the box.

The vaccine should always be kept out of the sight and reach of children.

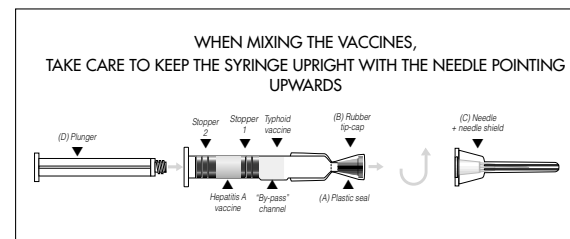
This leaflet was last approved in April 2005

© Registered Trademark

Instructions for use - Dual chamber syringe (See diagram below)

ViATIM® Suspension and solution for injection in a pre-filled dual chamber syringe
Hepatitis A (inactivated, adsorbed) and Typhoid polysaccharide vaccine.

1. Check that the plastic seal (A) covering the rubber tip-cap (B) is unbroken. Twist and remove the tip-cap in the direction of the arrows. This will break the plastic seal along the dotted line.
2. Attach needle and needle shield (C) to the syringe.
3. Screw the plunger rod (D) into the plunger stopper (stopper 2).
4. Shake the syringe; then mix the vaccine components by slowly pushing the plunger, keeping the needle upwards. The vaccine in the lower chamber moves into the upper chamber by means of the by-pass channel.
5. Shake vigorously until a homogeneous suspension is achieved.
6. Holding the needle shield at the tip, remove by pulling upwards without twisting.
7. Proceed immediately with the injection. A vein test may be carried out by pulling slightly on the plunger. The stoppers may separate but ensure that Stopper 2 does not reach the "by-pass channel" in order to avoid any leakage of liquid. If a blood vessel has been penetrated, blood will be pulled back into the syringe.



sanofi pasteur MSD