Package leaflet: Information for the user

ViATIM, Suspension and solution for suspension for injection in pre-filled syringe
Hepatitis A (inactivated, adsorbed) and Typhoid polysaccharide vaccine

Read all of this leaflet carefully before using this vaccine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- This vaccine has been prescribed for you only. Do not pass it on to others.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What ViATIM is and what it is used for

ViATIM is a vaccine. Vaccines are used to protect you against infectious diseases. This vaccine helps to protect against both typhoid fever and hepatitis A infection in people 16 years of age and older.

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 contains 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.

2. What you need to know before you use ViATIM

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.

Do not use ViATIM

- If you are allergic to the active substances or to any of the other ingredients of this vaccine (listed in section 6)
- If you are allergic to neomycin (an antibiotic used during vaccine production which may be present in the vaccine in small amounts)
- If you have an illness with a high temperature. Your vaccination should be delayed until you have recovered.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using ViATIM.

- If you have a poor immune response because you have had, or are having a course of treatment that can weaken your immune system such as corticosteroids, cytotoxic drugs or radiotherapy, your doctor or nurse may want to wait until the course of treatment has finished.
- If you have problems with your immune system due to human immunodeficiency virus (HIV) infection, you may be given ViATIM but the vaccine may not protect you as well as it protects people with normal immune systems.
- This vaccine 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 when you are given ViATIM, the vaccination may not work properly.
- This vaccine will not protect you against disease caused by *Salmonella* bacteria other than the particular type that causes typhoid fever.
- This vaccine cannot cause the infections against which it protects.
- As with any vaccine, not everyone who receives ViATIM will definitely be protected against hepatitis A and typhoid fever.

Fainting can occur (mostly in adolescents) following, or even before, any needle injection. Therefore tell your doctor or nurse if you or your child fainted with a previous injection.

Other vaccines or medicines and ViATIM

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

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 (another part of your body, e.g. the other arm or leg). ViATIM must not be mixed with any other vaccine in the same syringe.

The protection obtained when using ViATIM at the same time as immunoglobulins (antibodies obtained from blood donors), has not been assessed. If you need an injection of immunoglobulins, this may be given at the same time or within a few weeks of having ViATIM. However, you may not produce as much antibody to the hepatitis A virus as you would otherwise but it is likely that you will still be protected against infection.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this vaccine.
Although it is not thought that ViATIM could harm an unborn baby, your doctor or nurse will decide if you should be vaccinated now or after the baby has been born.

Driving and using machines

This vaccine has a minor influence on the ability to drive and use machines.
Dizziness has been reported in some people (less than 1 in 100 but more than 1 in 1000) after receiving ViATIM, so care should be taken when driving or using machines.

ViATIM contains phenylalanine and sodium

As this product contains phenylalanine, it may be harmful for people with phenylketonuria.
This vaccine contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially ‘sodium-free’.

3. How to use ViATIM

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

Always use this vaccine exactly as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

Dosage

The recommended dose is one millilitre of the mixed vaccine to people 16 years of age and older. Initial protection is achieved with one single dose of the vaccine.

This vaccine 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 long-term protection against hepatitis A. This booster will protect you against hepatitis A beyond ten years. The booster dose should be given within 36 months and preferably within 6 to12 months after the first dose.

This vaccine 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. However, if the first dose of hepatitis A vaccine was given as a combined typhoid and hepatitis A vaccine, then the second dose of combined vaccine should usually be given approximately 36 months after the first dose.

This vaccine 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 typhoid Vi polysaccharide vaccine.

The liquids in the two chambers 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 cloudy whitish suspension and that there are no unexpected particles in it.

Method and route of administration

This vaccine will be given as a slow injection into a muscle (intramuscular (IM) use) in the upper outer part of your arm. Your doctor or nurse will avoid giving you the injection either into the skin or into a blood vessel. This vaccine 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.

If you use more ViATIM than you should

In some cases, more than the recommended dose was used.
In these cases, when side effects were reported, they were of the same nature as those described in section 4.

If you have any further questions on the use of this vaccine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines and vaccines, ViATIM can cause side effects, although not everybody gets them.

Serious allergic reactions have been reported:

- Severe allergic reaction (anaphylaxis), which may include one or more of the following symptoms:
    - urticaria/skin rashes
    - swelling of the face and/or throat, difficulty in breathing, blue discolouration of the tongue or lips
    - low blood pressure, rapid heart rate and weak pulse, coldness of the skin, dizziness and potentially 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.

- Serum sickness:
    - joint pains, skin rashes, enlarged lymph glands and generally feeling unwell

When these symptoms occur, they usually develop 2-4 weeks after receiving the vaccine.
If these symptoms occur you must consult a doctor as soon as possible.

Very common reactions (may affect more than 1 in 10 people)
- pain where the vaccine was injected, sometimes lasting more than 3 days. Pain may be severe in up to 1 in 10 people (common)
- redness, swelling and hardness where the vaccine was injected. Swelling and hardness may be severe in up to 1 in 10 people (common)
- headache
- feeling weak
- feeling generally unwell
- aching muscles

Common reactions (may affect up to 1 in 10 people)
- feeling sick
- diarrhoea
- aching in the joints
- fever (a high temperature)

Uncommon reactions (may affect up to 1 in 100 people)
- itchiness of the skin
- rashes
- dizziness

Very rare reactions (may affect up to 1 in 10,000 people)
- a lump formed at the site of injection

Reactions of not known frequency (frequency cannot be estimated from the available data)
- worsening of asthma in people who already have asthma
- fainting in response to injection
- sensation of numbness or tingling on the skin
- rashes that are sometimes lumpy and itchy
- vomiting, stomach pains
- changes in blood tests that measure how the liver is working

Reporting of side effects in the UK
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

Reporting of side effects in Ireland
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store ViATIM

Keep this vaccine out of the sight and reach of children.

Do not use this vaccine after the expiry date which is stated on the carton and syringe label after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C - 8°C). Do not freeze. Keep the vaccine in the outer carton in order to protect from light.

This vaccine should not be used in case of unexpected particles in it.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What ViATIM contains

The active substances are:

- Hepatitis A virus GBM strain (inactivated)[1,2]……..160 antigen units
[1] produced in human diploid (MRC-5) cells
[2] adsorbed on aluminium hydroxide hydrated (0.3 milligram Al)
Aluminium hydroxide is included in this vaccine as an adsorbent. Adsorbents are substances included in certain vaccines to accelerate, improve and/or prolong the protective effects of the vaccine.
- *Salmonella typhi* (Ty 2 strain) capsular Vi polysaccharide ……25 micrograms

The other ingredients are sodium chloride, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate, 2-phenoxyethanol solution, formaldehyde, Medium 199 Hanks without phenol red (a mixture of aminoacids including phenylalanine (see section 2), mineral salts, vitamins and other components) supplemented with polysorbate 80, and water for injections.

What VIATIM looks like and contents of the pack

The vaccine is presented as a suspension and solution for suspension for injection in a pre-filled dual chamber syringe (0.5 ml of inactivated hepatitis A virus in one chamber and 0.5 ml of typhoid polysaccharide antigen in the other chamber) with or without a needle – pack size of 1 or 10. Not all pack sizes are marketed.

The inactivated hepatitis A vaccine is a cloudy, white suspension, and the typhoid polysaccharide vaccine is a clear, colourless solution.

Marketing Authorisation Holder:

Sanofi Pasteur Europe
14 Espace Henry Vallée
69007 Lyon
France

Distributed by:
United Kingdom:
Sanofi
410 Thames Valley Park Drive
Reading
Berkshire
RG6 1PT
UK
Tel: 0845 372 7101

Ireland:
sanofi-aventis Ireland T/A SANOFI
Citywest Business Campus
Dublin 24
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Tel: +353 (0) 1 4035 600

Manufacturer

The manufacturer responsible for batch release is Sanofi Pasteur at one of the following manufacturing sites:

Sanofi Pasteur,
Campus Mérieux,
1541 avenue Marcel Mérieux,
69280 Marcy l'Etoile,
France

or

Sanofi Pasteur,
Parc Industriel D'Incarville,
27100 Val de Reuil,
France

This medicinal product is authorised in the Member States of the EEA under the following names:

Member State	**Name**
Austria, Denmark, Finland, Germany, Greece, Iceland, Ireland, Luxemburg, Norway, Portugal, Sweden, The Netherlands, United Kingdom	ViATIM
Belgium	VACCIN COMBINE TYPHOIDIQUE POLYOSIDIQUE VI PURIFIE ET HEPATITE A
France, Spain	TYAVAX

This leaflet was last revised in 07/2019.

The following information is intended for healthcare professionals only:

Instructions for use – Dual chamber syringe (See diagram overleaf)
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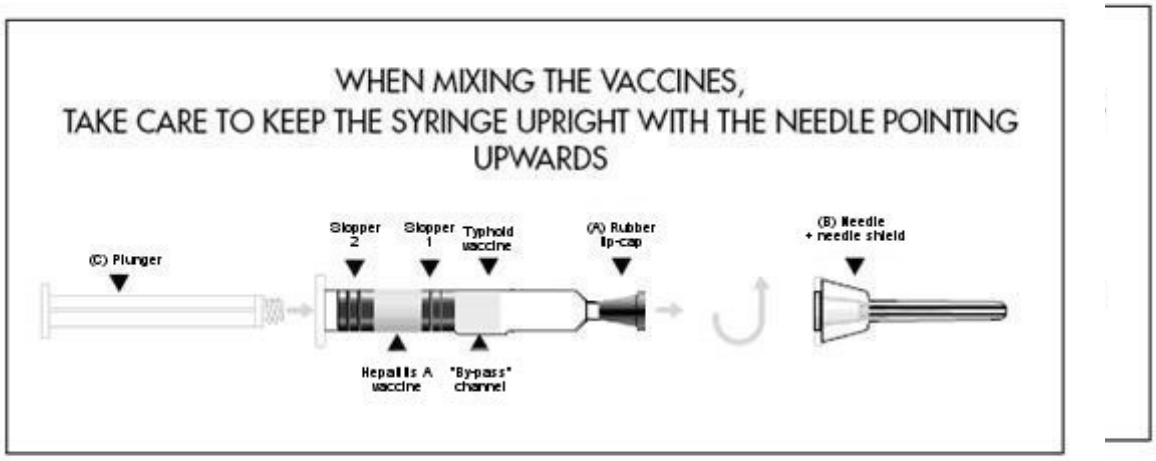
1. Remove the tip-cap (A).

2. Attach needle and needle shield (B) to the syringe.
3. Screw the plunger rod (C) 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.



See also section 3. How to use ViATIM