PATIENT INFORMATION LEAFLET FOR AVAXIM 160 U

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SCHEDULING STATUS: S4

AVAXIM 160U

suspension for injection

Inactivated Hepatitis A Vaccine, (inactivated, adsorbed)

Sugar free.

Preservatives: Phenoxyethanol – Ethanol (50 % v/v solution)

2-Phenoxyethanol 2,5 µL

Ethanol anhydrous 2,5 µL

Formaldehyde 12,5 µg

This vaccine contains polysorbate 80 and undetectable traces of neomycin.

Read all of this leaflet carefully before you start taking this medicine

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- Make sure that the whole immunisation schedule has been completed.

What is in this leaflet

1. What AVAXIM 160U is and what it is used for

AVAXIM 160U is a vaccine. This vaccine is indicated for the prevention of the infection caused by hepatitis A virus in adolescents from 16 years of age and in adults. AVAXIM 160 U can be used for primary immunisation or booster.

AVAXIM 160U confers immunity against hepatitis A virus by inducing antibody (anti-HAV) titres greater than those obtained after passive immunization with immunoglobulin.

Immunity (Anti-HAV) appears soon after the first injection, and 14 days after the vaccination, more than 90 % of immunocompetent subjects have anti-HAV above 20 mIU/mL.

One month after the first injection, 100 % of subjects are protected. Anti-HAV persist for at least 36 months and are reinforced after a booster injection.

2. What you need to know before AVAXIM 160U is given to you

Do not use AVAXIM 160U if you or your child have:

- Vaccination must be postponed in case of febrile or acute disease.
- Allergy to one of the vaccine components or a life threatening reaction after previous

administration of the vaccine or a vaccine containing the same components.

Warnings and precautions

Take special care with AVAXIM 160U:

- If you are allergic (hypersensitive) to formaldehyde or neomycin or other antibiotics of the same class.
- The vaccine does not provide protection against infection caused by hepatitis B virus, hepatitis C virus, hepatitis E virus or by other known liver pathogens.
- Because of the incubation period (time between infection with a virus to the start of symptoms) of hepatitis A, infection may be present but not clinically apparent at the time of vaccination. The effect of AVAXIM 160U administration in individuals, late in the incubation period of hepatitis A, has not been documented. In such cases vaccination should not modify the course of infection.
- As with any vaccine, vaccination with AVAXIM 160U may not protect 100 % of susceptible individuals (members of the population who are at risk of becoming infected by a disease)
- Immune suppressive treatments or a state of immune deficiency may lead to diminished immune response to the vaccine.
- Fainting may occur following, or even before any vaccination as an emotional and mental response to needle injection. Inform your health care provider if you have a fear of needles.

Other medicines and AVAXIM 160U:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

This vaccine may be administered simultaneously, but at separate sites, with a live attenuated yellow fever vaccine.

This vaccine can be administered simultaneously with the immunoglobulin provided that two different injection sites are used.

As the vaccine is inactivated, association with other vaccines at different injection sites does not generally result in any interaction.

This vaccine can be administered simultaneously, but at two different injection sites, with Polysaccharide typhoid vaccine.

This vaccine can be used as a booster dose in subjects previously vaccinated with another inactivated hepatitis A vaccine.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

The administration of AVAXIM 160U during pregnancy is not recommended. AVAXIM 160U should be given to pregnant women only if clearly needed, and following an assessment of the risks and benefits.

Caution must be exercised when you are a breastfeeding mother.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed. Do not drive or operate machines until you know how AVAXIM 160U affects you.

AVAXIM 160U contains ethanol, phenylalanine, potassium and sodium

- This medicine contains small amounts of alcohol (ethanol), less than 100 mg per dose. The

small amount of amount of alcohol in this medicine will not have any noticeable effects.

- This medicine contains 10 microgram phenylalanine in each 0,5 mL dose which is equivalent to 0,17 microgram/kg for a 60 kg person. Phenylalanine may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.
- This medicine contains less than 1 mmol of potassium (39 mg) and sodium (23 mg) per dose, i.e. it is essentially 'potassium-free' and 'sodium-free'.

3. How AVAXIM 160U will be administered

Dosage:

Recommended dosage is 0,5 mL for each injection.

The primary vaccination consists of one dose of vaccine followed by a booster dose 6 to 36 months apart, in order to confer long-term protection.

Data relative to long-term persistence of anti-HAV following vaccination with AVAXIM 160U are not currently available. Nevertheless, available data suggest that this booster dose will protect you against hepatitis A beyond 10 years.

In all cases follow the doctor's prescription strictly.

Method of administration

The vaccine must be injected by intramuscular route in order to minimise local reactions.

The recommended injection site is the deltoid muscle (upper arm muscle).

In exceptional cases the vaccine may be injected by subcutaneous routes in subjects suffering from thrombocytopenia (insufficient of platelets, a specific blood component with a role in blood clotting) or in patients at a risk of haemorrhage.

If you receive more AVAXIM 160U than you should

Since a health care provider will administer AVAXIM 160U, he/she will control the dosage. However, in the event of overdosage, your doctor will manage the symptoms of the overdosage.

If you forget one dose of AVAXIM 160U

If you miss a scheduled injection, it is important that you discuss it with your health care provider, who will decide when to give the missed dose.

It is important to follow the instructions from your health care provider.

If you have any further questions on the use of AVAXIM 160U, ask your health care provider.

4. Possible side effects

AVAXIM 160U can have side effects in certain persons.

Not all side effects reported for AVAXIM 160U are included in this leaflet. Should your general health worsen after being given AVAXIM 160U, please consult a doctor, pharmacist or other health care provider for advice.

Serious allergic reactions

Serious or even life-threatening allergic reactions (anaphylactic reactions, including shock) can always happen, even if they are very rare.

If any of the following symptoms occur after leaving the place where you received your injection, you must tell a doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to AVAXIM 160U. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache,
- nausea (feeling sick), decreased appetite, diarrhoea, vomiting (being sick), stomach pain,
- muscle and joint pains,
- injection site pain, abnormal physical weakness or lack of energy,
- muscle and joint pains,
- fever.

Less frequent side effects:

- injection site rash, injection site nodule,
- liver enzymes increased (mild and reversible).

Side effects occurring with an unknown frequency:

- fainting in response to the injection.
- urticaria (inflamed bumps on the skin), rashes associated or not with pruritis (itching),

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reactions were less frequently reported after the booster dose than after the first dose.

Reporting of side effects:

If you get any side effects, talk to a doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can report any side effects directly to Sanofi's Pharmacovigilance Unit

at za.drugsafety@sanofi.com (email) or 011 256 3700 (tel).

You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**" found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8.

5. How to store AVAXIM 160U

- Store in a refrigerator (2 °C – 8 °C).
- DO NOT FREEZE. DISCARD IF FROZEN.
- Store protected from light.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**

6. Contents of the pack and other information

What AVAXIM 160U contains:

Each immunising dose (0,5 mL) contains:

160 antigen units of inactivated** Hepatitis A virus (GBM strain) ***

** adsorbed on aluminium hydroxide (expressed as aluminium) 0,3 mg

*** Produced on MRC-5 human diploid cells

The other ingredients are 2-phenoxyethanol, aluminium hydroxide (hydrated), ethanol anhydrous, formaldehyde, hydrochloric acid (pH-adjuster), Hanks medium 199*, water for injections, polysorbate 80 and sodium hydroxide (pH-adjuster).

*hanks medium 199 without phenol is a complex mixture of amino acids (including phenylalanine), mineral salts (including potassium), vitamins and other components.

What AVAXIM 160U looks like and contents of the pack:

Cloudy, whitish suspension.

One 0,5 mL single dose pre-filled syringe (type 1 glass) closed by an elastomer plunger stopper (chlorobutyl) with a stainless steel attached needle.

Holder of Certificate of Registration:

sanofi-aventis south africa (pty) ltd

Hertford Office Park

Building I, 5th Floor, 90 Bekker Road

Vorna Valley, Midrand, 2196

South Africa

Tel: 011 256 3700

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