PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

AVAXIM 80

suspension for injection

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.

What is in this leaflet

1. What AVAXIM 80 is and what it is used for

2. What you need to know before AVAXIM 80 is given to your child

3. How AVAXIM 80 will be administered

4. Possible side effects

5. How to store AVAXIM 80

6. Contents of the pack and other information.

1. What AVAXIM 80 is and what it is used for

AVAXIM 80 is recommended for the prevention of the infection caused by hepatitis A virus in children aged from 12 months to 15 years included. This vaccine was demonstrated to bring out immunity against Hepatitis A virus within 2 weeks following the injection in over 95 % of individuals and in 100 % individuals before a booster dose. Antibodies against Hepatitis A virus persist for up to 7 years, are reinforced after the first booster dose.

2. What you need to know before AVAXIM 80 is given to your child

Do not use AVAXIM 80 if you or your child has:

- An allergy to the active substance, to one of the excipients, to neomycin (or to other antibiotics of the same class), to polysorbate (which may cause local skin reactions), to formaldehyde or shown hypersensitivity
  following a previous injection of this vaccine.
- A febrile illness, acute infection or progression of chronic disease: it is preferable to postpone vaccination.

Warnings and precautions

Take special care with AVAXIM 80:

- 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 80 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 80 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. In such cases it is recommended to postpone the vaccination until the end of the disease or treatment. Nevertheless, vaccination of subjects with chronic immunodeficiency such as HIV infection is recommended even if the antibody response might be limited.
- 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.

As with all injectable vaccines, the vaccine must be administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to these subjects.

In exceptional circumstances (e.g. in patients with thrombocytopenia (low platelets) or in patients at risk of bleeding), the vaccine may be injected by the subcutaneous route.

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following administration of the vaccine.

Prior to administration of any dose of AVAXIM 80, the parent or guardian of the recipient or the

adult recipient himself must be asked about his personal history, family history, and recent health status, including immunisation history, current health status and any adverse event after previous immunisation. In subjects who have a history of serious or severe reaction within 48 hours of a previous injection with a vaccine containing similar components, the course of the vaccination must be carefully considered.

Before the injection of any biological product, the person responsible for administration must take all precautions known for the prevention of allergic or any other reactions.

As a precautionary measure, epinephrine injection (1:1000) must be immediately available in case of unexpected anaphylactic or serious allergic reactions.

Other medicines and AVAXIM 80:

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

The vaccine may be administered simultaneously, at two different injection sites, with the routine booster dose of vaccine given to children during the second year of life, i.e. the various vaccines containing one or more of the following valences: diphtheria, tetanus, pertussis (acellular or whole cell), *Haemophilus influenzae* type b, and inactivated or oral poliomyelitis.

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

The vaccine may be administered concomitantly with a vaccine against measles, mumps and rubella, at two different injection sites.

This vaccine can be used as a booster dose in subjects who have received primary vaccination with another inactivated hepatitis vaccine.

This vaccine can be administered simultaneously with the immunoglobulin provided that two different injection sites are used. Seroconversion rates remain unmodified, but antibody titres may be lower than those observed after vaccination with AVAXIM 80 alone.

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 the vaccine during pregnancy is not recommended. AVAXIM 80 should be given to pregnant women only if clearly needed, and following an assessment of the risks and benefit.

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 80 affects you.

AVAXIM 80 contains ethanol, phenylalanine, potassium and sodium

- This medicine contains 2 mg of alcohol (ethanol) in each 0,5 mL 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 80 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. This booster dose will protect your child against hepatitis A beyond 10 years.

In all cases follow the doctor’s prescription strictly.

Method of administration

The vaccine is injected into a muscle in the upper outer part of the arm. In young children, it can be injected in the outer part of the thigh.

The vaccine must not be mixed with other vaccines in the same syringe.

If your child receives more AVAXIM 80 than he/she should

Since a health care provider will administer AVAXIM 80, 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 80

If your child misses 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 80, ask your health care provider.

4. Possible side effects

AVAXIM 80 can have side effects in certain persons.
Not all side effects reported for AVAXIM are included in this leaflet. Should your child's general health worsen after being given AVAXIM, 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 your child received his/her 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 your child has them, he/she may have had a serious reaction to AVAXIM 80. Your child may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice the following:

- fits (convulsions) with or without fever.

This is a serious side effect. Your child may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- abnormal crying (in babies),
- irritability, difficulty sleeping (insomnia),
- decreased appetite,
- injection site pain, injection site swelling and bruising, injection site redness (erythema), hardening of tissue or swelling at the injection site,
- generally feeling unwell,
- fever (temperature 38 °C or higher),
- feeling tired or very sleepy,
- headache, stomach pain, vomiting (being sick), diarrhoea, nausea (feeling sick),
- muscle or joint pain.

Less frequent side effects:

- rash, with or without itching,

Side effects occurring with an unknown frequency:

- fainting in response to the injection.

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

Reporting of side effects:

If your child gets 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 80

- 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.**
- Use immediately after opening.

6. Contents of the pack and other information

What AVAXIM 80 contains:

Each immunising dose (0,5 mL) contains:

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

** adsorbed on aluminium hydroxide (expressed as Al) 0,15 mg

*** produced on MRC-5 human diploid cells

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

polysorbate 80 and sodium hydroxide (pH-adjuster).

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

What AVAXIM 80 looks like and contents of the pack:

Avaxim 80 is a 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:

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