AVAXIM ADULT
INACTIVATED HEPATITIS A VACCINE

COMPOSITION
Each 0.5 mL dose contains:
- Hepatitis A* virus inactivated by formaldehyde ..... 160 antigen units**
- Aluminium hydroxide (expressed as aluminium) ..... 0.3 mg
- 2-phenoxyethanol ..... 2.5 µL
- Formaldehyde ..... 12.5 µg
- Hanks 199 medium*** ..... up to 0.5 mL
- Hydrochloric acid or sodium hydroxide to adjust the pH

* GBM strain cultured on MRC5 human diploid cells.
** In the absence of an international standardised reference, the antigen content is expressed using an in-house reference.
*** Hanks 199 medium is a complex mixture of amino acids, mineral salts, vitamins and other substances, diluted in water for injections; its pH is adjusted by adding hydrochloric acid or sodium hydroxide.

PHARMACEUTICAL DOSAGE FORM
Injectable suspension: 1 dose syringe (0.5 mL).

MARKETING AUTHORIZATION HOLDER AND MANUFACTURE
Sanofi Pasteur SA
2, avenue Pont Pasteur, F-69007, Lyon - France

INDICATIONS
This medicinal product is a VACCINE.
- This medicinal product is recommended in the prevention of infection caused by hepatitis A virus in adults over the age of 16 years.
- Vaccination against hepatitis A is recommended for subjects exposed to hepatitis A virus risks such as:
  * Non-immunized adults traveling in an endemic area (region where the hepatitis A virus is commonly found).
  * Adults professionally exposed to a risk of contamination: nursery personnel, boarders and staff of establishments and services for handicapped infants and children, sewage and water treatment personnel, food industry and catering personnel).
  * Adults in particular risk categories (haemophilia, multiple transfusion, IV drug dependency, homosexual practices).
- It does not protect against infection due to other types of hepatitis virus or to other known pathogens of the liver.

CONTRAINDICATIONS
This medicinal product MUST NOT BE USED in the following cases:
- In the event of fever, acute illness, chronic progressive disease (it is preferable to postpone vaccination).
- hypersensitivity to one of its components or following a previous injection.

If there is any doubt, it is essential to consult your doctor or your pharmacist.

SPECIAL WARNINGS
- Do not inject by the intravascular route: ensure that the needle does not penetrate a blood vessel.
- This vaccine is not to be injected into the buttocks (due to the presence of varying amounts of adipose tissue) nor administered intradermally, since these routes of administration may induce a reduced degree of immune response.
- Immunosuppressant treatment or a state of immune deficiency may lead to a diminished immune response to the vaccine.
- Vaccination may have no effect on the development of hepatitis A if administered during the incubation period of the disease.

PRECAUTIONS FOR USE
Use this medicinal product WITH CARE:
- In subjects with liver disease.
- In subjects who are hypersensitive to neomycin (each dose of vaccine contains trace amounts of neomycin).

If there is any doubt, do not hesitate to consult your doctor or your pharmacist.
Keep out of the reach of children.

SP/534508/A-1114

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DRUG INTERACTIONS AND OTHER INTERACTIONS
The vaccine may be administered simultaneously with immunoglobulins provided two different injection sites are used.
Since this vaccine is inactivated, it can be given at same time as other inactivated vaccines using a different injection site, without in general causing interference.
This vaccine can be administered at the same time as a recombinant hepatitis B vaccine, but two separates sites of injection should be used.
This vaccine can be used as a booster dose in subjects who have received primary vaccination with another inactivated hepatitis A vaccine.
In order to avoid the possible interactions between several medicinal products, any other ongoing treatment should be systematically reported to your doctor or to your pharmacist.

PREGNANCY - BREAST FEEDING
The effect of this medicinal on embryo-foetal development has not been assessed. As for any inactivated viral vaccine, however, it is unlikely that any adverse effects on the embryo or foetus would be observed. Nevertheless, this vaccine is not recommended in pregnant women.
As for any medicinal product, the decision to use this vaccine in pregnant or breast-feeding women should only be taken after a thorough evaluation of the expected risk-benefit.
The effect of administering this vaccine during breast feeding has not been studied and its use during feeding is therefore not recommended.

LIST OF THE EXCIPIENTS, KNOWN TO HAVE A RECOGNISED ACTION OR EFFECT IN SOME PATIENTS
Formaldehyde.

DOSAGE
The recommended dose is 0.5 mL for each injection.
The primary vaccination is performed with one single dose of vaccine followed by a booster injection: 6 to 12 months later for adults over 16 years of age.

METHOD AND ROUTE OF ADMINISTRATION
It is recommended that this vaccine be administered by the intramuscular route (IM) in order to minimize local reactions.
The recommended injection site is: the deltoid region (upper arm muscle) in adults.
Do not inject via the intravascular route: insure that the needle does not penetrate a blood vessel.
The vaccine should not be administered into the gluteal muscle of the buttocks (due to the presence of varying amounts of adipose tissue) nor intradermally, since these modes of administration may induce a lesser degree of immune response.
In exceptional cases, the vaccine may be administered subcutaneously in patients with thrombocytopenia (inadequate amount of platelets, a specific blood component with an important role in blood clotting) or in patients subject to haemorrhages.
This vaccine should not be mixed together with other vaccines in the same syringe.

SIDE EFFEECTS
Like any active product, this medicinal product may in certain persons cause effects which are disturbing to a greater or lesser extent:
- Local pain sometimes combined with redness. The appearance of a nodule at the injection site has been observed in very rare cases.
- Moderate fever, fatigue, headache, muscle or joint pains, and gastrointestinal upset have been the most commonly observed adverse effects.
- A mild reversible rise in liver enzymes (transaminases) has been observed on rare occasions.

Report to your doctor or to your pharmacist any unwanted and disturbing effect which might not be mentioned in this leaflet.

STORAGE
- Do not exceed the expiry date stated on the external packaging.

SPECIAL PRECAUTIONS FOR STORAGE
- Store between +2°C and +8°C (in a refrigerator). Do not freeze. Shelf life 36 moths

PACKAGE: Box of 1 pre-filled syringe 0.5 mL. Reg. No. DKI0159702343A1

Imported by: PT. Aventis Pharma, Jakarta, Indonesia for PT. BIO FARMA, Bandung

Harus dengan resep dokter

Pada proses pembuatannya bersinggungan dengan bahan bersumber babi

SANOFI PASTEUR

SAP / ID. number	: PI. AVAXIM 160 ADULT / 534508
Version number	: 6A
Country	: Indonesia
Date	: 30.01.2015
Dimensions	: 90 x 150 mm
Film code	: SP/534508/A-1114
Min. point size of text	: 7 pt
Colour	: PMS Pantone Black CVC
Type of Fonts	: Gill San Family
Material	: HVS Paper 60 g/m²
Type of Prefolded	: 3x Horizontal
Dimensions after folded	: 90 mm X 19 mm
Position of Visual Codes	: 9-10mm, 11-12mm, &17-18mm
Pharmacode	: 45081
Position of phramacode	: 34-34.5mm, 35.5-37mm, 38-38.5mm, 39.5-41mm, 42-43.5mm, 44.5-45mm, 46-46.5mm, 47.5-48mm, 49-49.5mm, 50.5-51mm, 52-52.5mm, 53.5-54mm, 55-56.5mm, 57.5-59mm, 60-60.5mm
Prepared by	: Rahmat Hafid

PEMERIKSAAN ARTWORK

Distribusi	Items to be check	Komentar	Paraf/Tanggal
Purchasing	Type & Quality of material used	Ok/Not Ok Ok setelah koreksi	
Product Manager	Artwork lay-out (correctness of teks, lay-out, type & Quality of material used)	Ok/Not Ok Ok setelah koreksi	
Registration	Correctness of text, registration number & storage condition	Ok/Not Ok Ok setelah koreksi	
Packaging	Dimension, lay out, die cut, folded and position for batch marking area	Ok/Not Ok Ok setelah koreksi	
Quality Control	Code bars, colours, storage condition & film code	Ok/Not Ok Ok setelah koreksi	
IQC	Artwork design based on PMS guide & film code	Ok/Not Ok Ok setelah koreksi	
Plant Logistic	Material code & implementation	Ok/Not Ok Ok setelah koreksi	