For the use only of a Registered Medical Practitioners or a Hospital or a Laboratory

Abridged Prescribing Information

Inactivated Hepatitis A Vaccine adsorbed I.P. AVAXIM 160 U

Suspension for injection in prefilled syringe

COMPOSITION

One dose (0.5 ml) contains: Hepatitis A virus, GBM strain (inactivated) .....160 units
Cultured on MRC-5 human diploid cells

Therapeutic indications

This vaccine is indicated for active immunization against infection caused by the hepatitis A virus in adolescents from 16 years of age and in adults. This vaccine should be administered in accordance with official recommendations.

DOSAGE AND ADMINISTRATION

Posology

The recommended dosage for subjects from 16 years of age is 0.5 ml.
The initial protection is obtained after one single injection.
In order to obtain a long-term protection against infections caused by the Hepatitis A virus, in adolescents from 16 years of age and in adults, a second dose (booster) should be administered, preferably between 6 and 12 months after the first vaccination and can be administered up to 36 months after the first vaccination. This vaccine can also be administered as a booster dose of the hepatitis A vaccination in subjects from 16 years of age who received a first injection with the combined typhoid fever (Vi purified polysaccharide) and hepatitis A (inactivated) vaccine between 6 and 36 months earlier.

Method of administration

- This vaccine must be administered by the intramuscular route (IM). The recommended injection site is the deltoid region.
- In exceptional cases, the vaccine may be administered by the subcutaneous route in patients with thrombocytopenia or in patients at risk of haemorrhage.
- The vaccine should not be administered into the buttocks because of the varying amount of fat tissue in this region,that may contribute to variability in effectiveness of the vaccine.
- Do not inject by the intravascular route: ensure that the needle does not penetrate a blood vessel.
- Do not inject by the intradermal route.

SAFETY RELATED INFORMATION

Contraindications

- Hypersensitivity to the active substance or to any of the excipients or to neomycin (that may be present as traces in each dose due to its use during the manufacturing process).
- Hypersensitivity following a previous injection of this vaccine.
- Vaccination should be postponed in case of severe acute febrile illness.

Pregnancy No reliable data are available on teratogenesis in animals.

Breast-feeding The use of this vaccine is possible during breast-feeding.

Special warnings and precautions for use

- As with all injectable vaccines, available appropriate medical treatment and subject monitoring are recommended in case of an anaphylactic reaction after vaccine administration.
- AVAXIM 160 U has not been studied in patients with impaired immunity.
- Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection, especially in adolescents. This may be accompanied by several neurological signs such as transient sight disorders, paraesthesia and tonic-clonic limb movements during the recovery phase. It is important that procedures be in place to avoid any injury from faints.
- Immunosupressive treatment or immunodeficiency may induce a decrease in the immune response to the vaccine.
  It is then recommended to wait until the end of treatment before vaccinating or to make sure the subject is well protected. Nevertheless, vaccination of subjects with chronic immunodeficiency such as HIV infection is recommended even though the antibody response might be limited.
- Because of the incubation period of hepatitis A, infection may already be present, although asymptomatic, at the time of vaccination. The effect of administering AVAXIM 160 U during the incubation period of hepatitis A has not been documented. In such a case, vaccination may have no effect on the development of hepatitis A.
- The use of this vaccine in subjects with liver disease should be considered with caution, as no studies have been performed in such subjects.
- As with all vaccines, a protective immune response may not be obtained in all vaccines.
- The vaccine does not protect against infection caused by hepatitis B, hepatitis C or hepatitis E viruses, or by other known liver pathogens.

ADVERSE REACTION

Nervous system disorders

Common:cephalalgia.

Not known: vasovagal syncope in response to injection.

Gastrointestinal disorders

Common: nausea, vomiting, appetite decrease, diarrhoea, abdominal pain.

Skin and subcutaneous tissue disorders

Not known: urticaria, rash associated or not with pruritus.

Musculoskeletal and connective tissue disorders

Common: myalgia, arthralgia.

General disorders and administration site conditions Very common: asthenia, mild injection site pain.

Common: mild fever.

Uncommon: injection site erythema.

Rare: injection site nodule.

For further information please contact: Registered office:- Sanofi Healthcare India Private Limited, Sanofi House, CT Survey No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai 400072

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