

HAVRIX 720 JUNIOR

→ sdh sesuai dg yg disetujui sbmnya hanya beda yg ditandai

QUALITATIVE AND QUANTITATIVE COMPOSITION

HAVRIX, hepatitis A virus vaccine is a sterile suspension containing formaldehyde-inactivated hepatitis A virus (HM175 hepatitis A virus strain) adsorbed onto aluminium hydroxide.

The virus is propagated in MRC-5 human diploid cells. Before viral extraction the cells are extensively washed to remove culture medium constituents. A virus suspension is then obtained by lysis of the cells followed by purification using ultrafiltration techniques and gel chromatography. The virus is inactivated with formalin.

HAVRIX meets the World Health Organisation requirements for the hepatitis A vaccine (inactivated).

HAVRIX contains a purified sterile suspension of inactivated hepatitis A virus; the viral antigen content is determined by an ELISA test.

HAVRIX 1440 adult is standardised to ensure a viral antigen content of not less than 1440 ELISA units (E.U.) of viral antigens, in a 1.0 ml dose volume.

HAVRIX 720 Junior is standardised to ensure a viral antigen content of not less than 720 E.U. of viral antigens, in a 0.5 ml dose volume.

CLINICAL PARTICULARS

Therapeutic Indications

HAVRIX is indicated for active immunisation against hepatitis A virus (HAV) infection in subjects at risk of exposure to HAV.

HAVRIX will not prevent hepatitis infection caused by other agents such as hepatitis D virus, hepatitis C virus, hepatitis E virus or other pathogens known to infect the liver.

In areas of low to intermediate prevalence of hepatitis A, immunisation with HAVRIX is particularly recommended in subjects who are, or will be, at increased risk of infection such as:

Travellers. Persons travelling to areas where the prevalence of hepatitis A is high. These areas include Africa, Asia, the Mediterranean basin, the Middle East, Central and South America.

Armed Forces. Armed Forces personnel who travel to higher endemicity areas or to areas where hygiene is poor have an increased risk of HAV infection. Active immunisation is indicated for these individuals.

Persons for whom hepatitis A is an occupational hazard or for whom there is an increased risk of transmission. These include: employees in day-care centres, nursing, medical and paramedical personnel in hospitals and institutions, especially gastroenterology and paediatric units, sewage workers, food handlers, among others. Persons at increased risk due to their sexual behaviour. Homosexual, persons with multiple sexual partners.

Abusers of injectable drugs.

Contacts of Infected Persons. Since virus shedding of infected persons may occur for a prolonged period, active immunisation of close contacts is recommended.

Specific population groups known to have a higher incidence of hepatitis A. For example American Indians, Eskimos, recognised community-wide HAV epidemics.

Subjects with chronic liver disease or who are at risk of developing chronic liver disease (e.g. Hepatitis B (HB) and hepatitis C (HC) chronic carriers and alcohol abusers). Hepatitis A tends to compromise the outcome of the chronic liver disease.

In areas of intermediate to high prevalence of hepatitis A (e.g. Africa, Asia, the Mediterranean basin, the Middle East, Central and South America) susceptible individuals may be considered for active immunisation.

Posology

Adults from 19 years onwards.

A single dose of HAVRIX 1440 adult (1.0 ml suspension) is used for primary immunisation.

Children and adolescents from 1 year up to and including 18 years of age.

A single dose of HAVRIX 720 Junior (0.5 ml suspension) is used for primary immunisation.

A booster dose is recommended at any time between 6 and 12 months after a single dose of HAVRIX™ 1440 adult or HAVRIX 720 Junior in order to ensure long term protection.

Method of administration

HAVRIX is for intramuscular administration. Do not inject intravenously, intradermally or subcutaneously. The vaccine should be injected in the deltoid region in adults and children. In the anterior lateral part of the thigh in infants.

Contra-indications

With other vaccines, the administration of HAVRIX should be postponed in subjects suffering from a severe febrile illness. The presence of a minor infection, however, is not a contra-indication for vaccination.

HAVRIX should not be administered to subjects with known hypersensitivity to any component of the vaccine, or to subjects having shown signs of hypersensitivity after previous administration of HAVRIX.

Special warnings and special precautions for use

It is possible that subjects may be in the incubation period of a hepatitis A infection at the time of vaccination. It is not known whether HAVRIX will prevent hepatitis A in such cases.

In haemodialysis patients and in subjects with an impaired immune system, adequate anti-HAV antibody titres may not be obtained after a single dose of HAVRIX and such patients may therefore require administration of additional doses of vaccine.

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available for treatment in case of a rare anaphylactic event following the administration of the vaccine. For this reason, the vaccine should remain under medical supervision for 30 minutes after vaccination.

HAVRIX should be administered with caution to people with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to these subjects.

The vaccine should not be administered intramuscularly in the gluteal region or subcutaneously/intradermally since administration by these routes may result in a less than optimal anti-HAV antibody response.

HAVRIX should under no circumstances be administered intravascularly.

Interaction with other medications and other forms of interaction

Since HAVRIX is an inactivated vaccine its concomitant use with other inactivated vaccines is unlikely to result in interference with the immune responses.

When concomitant administration of other vaccines is considered necessary, the vaccines must be given with different syringes and at different injection sites.

Concomitant administration of typhoid, yellow fever, cholera (injectable) or tetanus does not interfere with HAVRIX immune response.

Pregnancy and lactation

The effect of HAVRIX on fetal development has not been assessed. However, as with all inactivated viral vaccines the risk to the fetus are considered to be negligible. HAVRIX should be used during pregnancy only when clearly needed.

The effect on breastfed infants of the administration of HAVRIX to their mothers has not been evaluated in clinical studies. The risk/benefit ratio of HAVRIX administration should therefore be evaluated with caution in breastfeeding women, although the risk can be considered as negligible.

Undesirable effects

HAVRIX is well tolerated. In controlled clinical studies, signs and symptoms were monitored in all subjects for four days following the administration of HAVRIX. A checklist was used for this purpose. The vaccines were also expected to report any clinical events occurring during the study period.

The frequency of solicited adverse events was lower following the booster dose of HAVRIX™. Most events reported were considered by the subjects as mild and did not last for more than 24 hours. The frequency of solicited adverse events following the administration of HAVRIX is not different from the frequency of solicited adverse events reported following the administration of other aluminium adsorbed purified antigen vaccines.

Of the local solicited adverse events the most frequently reported was injection site soreness (less than 0.5% reported as severe) which resolved spontaneously. Other local solicited adverse events reported were mild redness and swelling, with a frequency of about 4% of all vaccinations.

The systemic adverse events reported by vaccinees were essentially mild, most did not last for more than 24 hours and included headache, malaise, weakness, fever, nausea, and loss of appetite. These events were reported with a frequency varying between 0.0% and 12.0% of vaccinations. All events resolved spontaneously.

The nature of the signs and symptoms observed in children is similar to that of adults, however, these have been reported less frequently.

PHARMACOLOGICAL PROPERTIES

Relevant information for vaccinees

HAVRIX protects against hepatitis A by inducing specific anti-HAV antibodies.

In clinical studies involving subjects of 18-50 years of age, specific humoral antibodies against HAV were detected in more than 88% of vaccinees at day 15 and 99% at month 1 following administration of a single dose of HAVRIX 1440 Adult.

In clinical studies involving subjects of 1-18 years of age, specific humoral antibodies against HAV were detected in more than 93% of vaccinees at day 15 and 99% of vaccinees one month following administration of HAVRIX 720 Junior.

To obtain long term immunity a booster dose is recommended.

Primates exposed to the virulent heterologous hepatitis A strain were vaccinated 2 days after exposure. This post exposure vaccination resulted in total protection of the animals.

PHARMACOLOGICAL PARTICULARS

Incompatibilities

HAVRIX should not be mixed with other vaccines in the same syringe.

Shelf-life

The expiry date of the vaccine is indicated on the label and packaging.

Special precautions for storage

Vaccine should be stored at +2°C to +8°C.

Do not freeze; discard if vaccine has been frozen.

Instructions for use/handling

The content, upon storage, may present a thin white deposit with a clear colourless supernatant. The vaccine should be inspected visually for any foreign particulate matter and/or variation of physical aspect prior to administration. Before use of HAVRIX, the vial/syringe should be well shaken to obtain a slightly opaque white suspension. Discard the vaccine, if the content appears off-white.

Presentations

Pack of one monodose pre-filled syringe 0.5ml, Reg. No. DR1xxxxxx

HARUS DENGAN RESEP DOKTER
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