

PrevaHAV™

Inactivated, Hepatitis A Vaccine BP

Presentation

PrevaHAV™ for adult: Each vial contains 1 ml of inactivated Hepatitis A vaccine BP containing ≥ 500 U of the Hepatitis A viral antigen propagated in the human diploid cell culture and adsorbed on Aluminium hydroxide.

PrevaHAV™ for pediatric: Each vial contains 0.5 ml of inactivated Hepatitis A vaccine BP containing ≥ 250 U of the Hepatitis A viral antigen propagated in the human diploid cell culture and adsorbed on Aluminium hydroxide.

Description

PrevaHAV is a purified sterile suspension of inactivated Hepatitis A vaccine derived from Hepatitis A virus cultured in human diploid cell followed by harvest, purification, inactivation by formaldehyde and Aluminium hydroxide adsorption.

Indications and uses

The vaccine is indicated for the active immunization of adults and children from 12 months of age against infection caused by Hepatitis A virus.

Dosage and administration

Hepatitis A vaccine should be given intramuscularly only. Do not inject it intravenously. The primary immunization consists of two doses, the first dose is at the selected date and the second dose will be at 6 months later.

• Children 12 months to 15 years: The recommended dose is 0.5 ml

First dose: At elected date

Second dose: 6 months after first dose

• Children 16 years and above: The recommended dose is 1 ml

First dose: At elected date

Second dose: 6 months after first dose

Method of administration

Hepatitis A vaccine should be injected intramuscularly in the deltoid region in adults and children and in the anterolateral part of the thigh in young children under 1 year. The vaccine should not be administered intramuscularly in the gluteal region or subcutaneously/intradermally since administration by these routes may result in less antibody response than optimal.

Hepatitis A vaccine should be inspected visually for any foreign particulate matter and/or discoloration prior to administration. Before use, the vial should be well shaken to obtain a slightly milky-white suspension. The vaccine must be used as supplied.

Contraindications

- People who are allergic to any component of the vaccine
- People who suffer from serious diseases, fever and any immune disease

Co-administration

Since Hepatitis A vaccine is an inactivated vaccine, its concomitant use with other inactivated vaccines is unlikely to result in interference with 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 Hepatitis B, typhoid, yellow fever, cholera (injectable) or tetanus vaccine does not interfere with Hepatitis A vaccine immune response. Concomitant administration of Hepatitis A vaccine and human immune globulin may be considered when a subject is at risk of being exposed to Hepatitis A before adequate antibody titre can be reached. Hepatitis A vaccine and human immune globulin should be administered at separate injection sites.

Pregnancy and lactation

Pregnancy: The vaccine should be given to a pregnant woman only if clearly needed.

Lactation: The vaccine should be used with caution for lactating women.

Side effects

Reactions at the site of injection are common but can be recovered within 72 hours without any treatment. Some of the mild and temporary adverse reactions are: pain and redness at the site of injection, fever after vaccination.

Precautions

- Shake well before use
- The product should be used with caution for people who or whose family has the history of convulsion or epilepsy, chronic diseases and allergic symptoms
- Do not use the product if any crack of the container, foreign particulate matter, or out of expiry date
- This product should be used immediately after opening
- Adrenaline and other first aid medicines should be prepared at the vaccination place in serious allergic reaction. The people after vaccination should remain under medical supervision for 30 minutes
- The vaccine must not be frozen

Overdose

Not applicable.

Storage

- Keep out of the reach and sight of children
- Store and transport at $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$
- Protect from light

Commercial Pack

PrevaHAV™ for adult: Each box contains 1 vial containing 1 ml inactivated Hepatitis A Vaccine BP and 1 sterile disposable syringe.

PrevaHAV™ for pediatric: Each box contains 1 vial containing 0.5 ml inactivated Hepatitis A Vaccine BP, 1 sterile disposable syringe and 2 needles.

Manufactured by
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V.N. 01