Freeze-dried Live Attenuated Hepatitis A Vaccine

BIOVAC™- A

SC
USE ONLY

WOCKHARDT

COMPOSITION
Made from working seed virus the H_2 - attenuated strain of HAV, cultured in Human diploid cells.

Specification: After re-dissolved in vial to form 0.5 ml solution (one single dose), the live vaccine content should not be less than 6.5 $LgCCID_{50}$.

DESCRIPTION
Hepatitis A vaccine is a freeze-dried, live attenuated vaccine. The vaccine is prepared from the H_2 attenuated strain of the Hepatitis A virus (HAV), propagated in human diploid cells through a series of technological process including culture, harvesting, purification, preparation, filling and freeze-drying.

PHARMACOLOGY
Hepatitis A Vaccine confers immunity against HAV infection by the induction of specific antibodies against the virus. The vaccine confers immunity against HAV virus by inducing antibody titres greater than those obtained after passive immunization with immunoglobulin.

INDICATIONS
The vaccine is indicated for active immunization against infection caused by HAV in persons over 1 year of age. It can be used for primary immunization. Hepatitis A vaccine is recommended for pre-exposure prophylaxis of individuals at increased risk of infection and post-exposure prophylaxis. Thus the vaccine is indicated in the following conditions:

- Residents of communities with high endemic rates or recurrent outbreaks of Hepatitis A;
- Travellers to countries where Hepatitis A is endemic, especially when the travel involves rural or primitive conditions;
- Members of the armed forces, emergency relief workers and others likely to be posted abroad at short notice to areas with high rates of HAV infection;
- Residents and staff of institutions where there is an ongoing problem with HAV transmission;
- Inmates of correctional facilities in which there is an ongoing problem with HAV infection;
- People with life style determined risks of infection, including those engaging in oral or intravenous illicit drug use in unsanitary conditions;
- People with chronic liver disease who may be at increased risk of fulminant hepatitis A;
- Patients with hemophilia A or B receiving plasma-derived replacement clotting factors;
- Zoo-keepers, veterinarians and researchers who handle non-human primates;

CONTRAINDICATIONS
1. Hypersensitivity to the vaccine or any component of the formulation.
2. Acute infectious disease or other serious illness.
3. Acute febrile illness with temperature above 37.5 degree centigrade.
4. Immunological deficiency states.
5. A history of anaphylaxis or any other serious allergic reaction to vaccines.

A minor afebrile illness or mild upper respiratory tract infection is not usually a reason to defer immunization with the vaccine.

WARNINGS
Hepatitis A Vaccine does not provide protection against infection caused by hepatitis B virus, hepatitis C virus, delta virus, hepatitis E virus, or by other liver pathogens.
Immunocompromised persons (from disease or treatment) may not obtain the expected immune response.
Because of the incubation period of Hepatitis A, infection may be present at the time of vaccination; if so, the vaccine may be ineffective.

PRECAUTIONS
1. The product is a live attenuated vaccine; the contact of the vaccine with any disinfectant should be avoided during manipulation.
2. The product should not be used if it is found to have a crack in the vial, or unclear label, or turbidity after dissolution or the presence of foreign body.
3. The vaccine should be used completely within 1 hr after the vial is opened.
4. The vaccine should be given more than 3 months after gamma globulin administration.
5. As with any parenteral vaccine, epinephrine should be available for use in case of anaphylaxis or anaphylactoid reaction.
6. Prior to injection, with any vaccine, all known precautions should be taken to prevent adverse reactions. This includes a review of the patient's history with respect to possible hypersensitivity to the vaccine.

7. A separate syringe and needle must be used for each patient to prevent the transmission of infectious agents from person to person.

8. Use by pregnant women is not recommended.

ADVERSE REACTIONS

Adverse events to Hepatitis A vaccine are usually mild and confined to the first few days after vaccination with spontaneous recovery.

Local

* pain at the site of injection.
* redness,
* swelling, hematoma, induration/edema,
* pruritus

These usually subside within 72 hours and no specific treatment is needed. Relevant treatment may be given whenever needed.

Systemic

* fever (>37.5°C axillary)
* asthenia/drowsiness
* headache, myalgia/arthralgia,
* gastrointestinal disorders,
* behavioural changes, skin disorders

DOSAGE

Add 0.5 ml sterile water for injection and shake well till the powder completely dissolves. Then inject a single dose of 0.5 ml subcutaneously over the deltoid muscle of upper arm. No booster dose is required. After one year of age, only one single dose for child and adult.

ADMINISTRATION

Parenteral biological products should be inspected visually for extraneous particulate matter and/or discolouration before administration. If these conditions exist, the product should not be administered.
Before injection, the skin over the site to be injected should be cleansed with a suitable germicide.
Administer the vaccine **subcutaneously**. The preferred site is over the deltoid muscle. Do not administer over the buttocks.
After insertion of the needle, aspirate to ensure that the needle has not entered a blood vessel. **Do not inject intravenously.**

STORAGE & TRANSPORTATION

Hepatitis A Vaccine should be kept and transported at a temperature +2°C to +8°C in a dark place. Do not use vaccine beyond the expiration date.

PRESENTATION :

BIOVAC-A : Pack of 0.5 ml vial of Biovac-A alongwith 0.5 ml ampoule of sterile water for injection.

Manufactured by
Zhejiang Pukang
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Imported & Marketed in India by
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