



## OVERVIEW OF LIVE ATTENUATED HEPATITIS-A VACCINE

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Article Received on 11/05/2021

Article Revised on 02/06/2021

Article Accepted on 23/06/2021

### DESCRIPTION

Hepatitis A vaccine is a freeze-dried, live attenuated vaccine. The vaccine is prepared from the H<sub>2</sub> 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 gives immunity against HAV virus by inducing antibody titers greater than those obtained after passive immunization with immunoglobulin.

### COMPOSITION

Each 0.5 ml/dose contains Hepatitis A Live attenuated vaccine > 6.5 LgCCID<sub>50</sub>  
Inactive: Trehalose - 24mg,  
Dextran-40 - 4.5mg,  
Sorbitol - 9mg,  
Mannitol - 6mg,  
Amino acids salts Eq. solution - 11.73mg  
Made from working seed virus the H<sub>2</sub>- attenuated strain of HAV, cultured in Human diploid cells.

### INDICATIONS

The vaccine is indicated for active immunization against Hepatitis-A in adults and children above 1 year age.

### 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 may not obtain the expected immune response.

If infection is present at the time of vaccination, 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 vaccination.
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 given more than 3 months after gamma globulin administration.
4. As with any parenteral vaccine, epinephrine should be available for use in case of anaphylaxis reaction.
5. Prior to injection, with any vaccine, all known precautions should be taken to prevent adverse reactions. This includes review of the patient's history with respect to possible hypersensitivity to the vaccine.
6. A separate syringe and needle must be used for each patient to prevent the transmission of infectious agents from person to person.
7. Use by pregnant women is not recommended.

### DOSAGE AND ROUTE OF ADMINISTRATION

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.

A single dose of the Hepatitis-A live attenuated vaccine imparts adequate immune protection in individuals above 1 year of age and a booster dose is usually not required.

**PRECAUTION WHILE ADMINISTRATION**

Parenteral biological products should be inspected visually for extraneous particulate matter and/or discoloration 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****ADVERSE REACTIONS**

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

**• LOCALLY**

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)

Drowsiness

Headache, myalgia, arthralgia

Gastrointestinal disorders

Behavioral changes, skin disorders

**SHELF LIFE**

Shelf Life of Product: 24 months

Shelf Life after reconstitution: The vaccine should be used completely within 1 hour after the vial is opened and/or reconstituted.

**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.