

Registration No. 1C 8/53 (NB)

Importer / Manufacturer: Biogenetech Co., Ltd. / Zhejiang Pukang Biotechnology Co. Ltd.

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICAL PRODUCT

MEVAC-A

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

This vaccine is made from master seed virus, H₂-attenuated strain of HAV, cultured in human diploid cells.

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 LgCCID₅₀.

3. PHARMACEUTICAL FORM

Freeze-dried, live attenuated vaccine

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

The vaccine is indicated for active immunization against infection caused by HAV in persons over one and half 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:

1. Residents of communities with high endemic rates or recurrent outbreaks of HAV;
2. Travellers to countries where Hepatitis A is endemic, especially when the travel involves rural or primitive conditions;
3. 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;
4. Residents and staff of institutions where there is an ongoing problem with HAV transmission;
5. Inmates of correctional facilities in which there is an ongoing problem with HAV infection;
6. People with life style determined risks of infection, including those engaging in oral or intravenous illicit drug use in unsanitary conditions;
7. People with chronic liver disease who may be at increased risk of fulminant hepatitis A;
8. Zoo-keepers, veterinarians and researchers who handle non-human primates.

4.2 Posology and method of administration

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 and half 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.

4.3 Contraindication

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
6. Patients with Hemophilia A

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

4.4 Special warnings and precautions for use

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 reconstitution.
4. The vaccine should be given more than 1 month 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.

4.5 Interaction with other medical products and forms of interaction

N/A

4.6 Pregnancy and lactation

Use by pregnant women is not recommended

4.7 Effects on the ability to drive and use machines

N/A

4.8 Undesirable effects

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 and 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/arthritis, gastrointestinal disorders, behavioural changes, skin disorders.

4.9 Overdose

N/A

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic properties

N/A

5.3 Preclinical safety data

N/A

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

L-Arginine, L-Tyrosine, L-Histidine, L-Isoleucine, L-Leucine, L-Lysine, L-Methionine, L-Phenylalanine, L-Tryptophan, L-Valine, Magnesium Sulfate, Lactose, Gelatin, Water for Injection

6.2 Incompatibilities

N/A

6.3 Shelf life

24 months

6.4 Special precautions for storage

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

6.5 Nature and contents of container

10 vials of lyophilized powder (single dose) with 10 ampoules of diluent (0.5 ml/ampoule)

6.6 Special precautions for disposal and other handling

N/A

7. MARKETING AUTHORISATION HOLDER

Biogenetech Co., Ltd.

18 Soi Udomsuk 37, Sukhumvit 103 Rd., Bangjak, Prakanong, Bangkok, 10260 THAILAND

8. MARKETING AUTHORISATION NUMBER(S)

1C 8/53 (NB)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

April 2, 2010

10. DATE OF REVISION OF THE TEXT

September 19, 2018