For the use only of a Registered Medical Practitioner or a hospital or a laboratory

Dr.Reddy's

BIOVAC® A

Freeze-Dried Live attenuated Hepatitis A Vaccine

Enquire the history of allergy before vaccination. People who are allergic to any ingredients in the vaccine, including excipients such as dextran 40 and gentamicin sulfate, should not be vaccinated.

1. Generic Name

Hepatitis A (Live) Vaccine, Freeze-dried

2. Qualitative and Quantitative Composition

Each 0.5 ml/dose contains:

Hepatitis A Live attenuated vaccine > 6.5 Lg CCID50 Inactive:

Trehalose **24mg**
Dextran-40 ..... **4.5mg**
Sorbitol **9mg**
Mannitol **6mg**
Amino acids salts Eq. solution ..... **. 11.73mg**

Made from working seed virus the H2- attenuated strain of HAV, cultured in Human diploid cells.

3. Dosage form and Strength

Pack of 0.5 ml vial of BIOVAC-A along with 0.5 ml ampoule of sterile water for injection

4. Clinical Particulars

4.1 Therapeutic Indication

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

4.2 Posology and method of administration

Posology

Adults and children above 1 year age

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 immunoprotection in individuals above 1 year of age and a booster dose is usually not required.

Method of 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 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.

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

- The product is a live attenuated vaccine; the contact of the vaccine with any disinfectant should be avoided during manipulation.
- 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.
- The vaccine should be given more than 3 months after gamma globulin administration.
- As with any parenteral vaccine, epinephrine should be available for use in case of anaphylaxis or anaphylactoid reaction.
- 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.
- A separate syringe and needle must be used for each patient to prevent the transmission of infectious agents from person to person.
- Use by pregnant women is not recommended.

4.5 DRUG INTERACTIONS

If Biovac A is used in individuals with malignancies or those receiving immunosuppressive therapy or who are otherwise immunocompromised, the expected immune response may not be obtained.

4.6 Use in special populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)

Pregnancy

There are no or limited amount of data from the use of this vaccine in pregnant women. Animal studies are insufficient with respect to reproductive toxicity. The use of this vaccine may be considered during pregnancy, if necessary.

Breast-feeding

It is unknown whether this vaccine is excreted in human milk. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

Fertility

No fertility data are available.

4.7 Effects on ability to drive and use machines

BiovacAis expected to have no or negligible influence on the ability todrive anduse machines.

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.

Common adverse reactions:

1. Generally, pain and tenderness may appear at the injection site within 24 hours after vaccination. In most cases, it disappears within 2 to 3 days without treatment.

2. Generally, a transient fever reaction may occur within 1 to 2 weeks after vaccination. Most of them are mild fever reactions, which usually relieve after 1 to 2 days without treatment. Take proper rest if necessary, drink plenty of water, keep warm, and prevent secondary infections. For those who have moderate fever reactions or fever longer than 48 hours, physical methods or drugs can be used to treat symptomatically.

3. After vaccination, skin rashes occasionally appear, no special treatment is needed, and symptomatic treatment can be given if necessary.

Rare adverse reactions:

Severe febrile reactions: physical methods and medications should be used to treat symptomatically to prevent febrile convulsions.

Extremely rare adverse reactions:

1. Anaphylactic shock and laryngeal edema: generally occur within 1hour after vaccination. Rescue measures such as epinephrine injection should be used for treatment in time.

2. Allergic rash: generally, urticaria occurs within 72 hours after vaccination. When a reaction occurs, you should seek medical treatment in time and give anti-allergic treatment.

3. Allergic purpura: if allergic purpura appears, you should seek medical treatment in time, and use corticosteroids medicines to give anti-allergic treatment. Improper or untimely treatment may cause secondary purpura nephritis.

4.9 Overdose

There are no data with regard to overdose.

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

Not applicable to vaccine products.

6. Non Clinical properties

6.1. Animal Toxicology and Pharmacology

Animal Toxicology

Non-clinical toxicology data reveal no special hazard for humans based on conventional studies of acute and long term toxicity, local muscle stimulation test, allergy test, Teratogenic and reproductive developmental toxicity test and tumorigenicity test.

Pharmacology

Non-clinical pharmacodynamic study: In the challenge test of rhesus monkeys, Biovac was challenged by wild virus strains "He-32" five months after being immunized with rhesus monkeys. No abnormal SGPT/ALT and LDH5 were detected in the experimental monkeys, and there were no symptoms related to hepatitis, and the titer of serum anti-Hepatitis A virus antibody increased.

7. DESCRIPTION

Hepatitis A Vaccine is a freeze-dried live attenuated vaccine. The vaccine is prepared from the H2 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.

8. PHARMACEUTICAL PARTICULARS

8.1 INCOMPATIBILITIES:

Not applicable

8.2 SHELF LIFE:

Shelf life of product: 24 months

Shelf life after first opening the container / shelf life after reconstitution: The vaccine should be used completely within 1hr after the vial is opened and /or reconstituted.

8.3 PACKAGING INFORMATION:

BIOVAC-A: Pack of 0.5ml vial of BIOVAC-A along with 0.5 ml ampoule of sterile water for injection.

8.4 STORAGE AND HANDLING INSTRUCTIONS:

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.

9. PATIENT COUNSELLING INFORMATION

Enquire the history of allergy before vaccination. People who are allergic to any ingredients in the vaccine, including excipients such as dextran 40 and gentamicin sulfate, should not be vaccinated.

Before administration, healthcare providers should inform patients, parents and guardians of the benefits and risks of the vaccination with BIOVAC A vaccine.

Prior to the administration of BIOVAC A vaccine health care providers should ask patients, parents and guardians about the recent health status of the patient to be immunized.

BIOVAC A may be administered to persons travelling to endemic or epidemic areas.

A single dose of the hepatitis A live attenuated vaccine imparts adequate immunoprotection in individuals above 1 year of age and booster dose is usually not required.

10. DETAILS OF MANUFACTURER

Zhejiang Pukang Biotechnology Co., Ltd.
No. 587 Binkang Road, Binjiang District
Hangzhou, 310053, China.
Exported By: Shenzhen Mellow Hope
Pharm Industrial Co., Ltd.

11. DETAILS OF PERMISSION OR LICENCE NUMBER WITH DATE

Permission no.: IMP/BIO/21/000090 Dated 25-OCT-2021

12. DATE OF REVISION:

July 2024

13. IMPORTED AND MARKETED BY

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