SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Medical Product

PrevaHAV Vaccine

Inactivated Hepatitis A vaccine

2. Qualitative and quantitative composition

Adult Dose: Each vial (1 ml) contains ≥ 500 U of the Hepatitis A viral antigen propagated in the human diploid cell culture and adsorbed on Aluminium hydroxide.

Pediatric Dose: Each vial (0.5 ml) contains ≥ 250 U of the Hepatitis A viral antigen propagated in the human diploid cell culture and adsorbed on Aluminium hydroxide.

3. Pharmaceutical form

Suspension for injection

4. Clinical Particulars

4.1 Therapeutic indications

The vaccine is indicated for the active immunization of adults and children from 12 months of age against infection caused by Hepatitis A virus. The vaccine is particularly indicated for those at increased risk of infection or transmission.

4.2 Posology and method of administration

Posology

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/adolescents (1-15 years)

The recommended dose is 0.5 ml

Adults (16 years and over)

The recommended dose is 1 ml

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.

4.3 Contraindication

Hypersensitivity to the active substance, to any of the excipients
People who are allergic to any component of the vaccine
People who suffer from serious diseases, fever and any immune diseases

4.4 Special warnings and precautions for use

- Immunization should be postponed in subjects suffering from an acute severed febrile illness. The presence of a minor infection, such as a cold, should not result in the deferral of vaccination.
- Reactions at the site of injection are common but can be recovered within 72 hours without any treatment.
- 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 product should be used with caution for people who or whose family has the history of convulsion or epilepsy, chronic diseases and allergic symptoms
- The product should not be used if any crack of the container, foreign particulate matter, or out of expiry date
- This product should be used immediately after opening. The product should be shaken before use and the vaccine must not be frozen.

4.5 Interaction with other medical products and forms of interaction

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 immunoglobulin 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 immunoglobulin should be administered at separate injection sites.

4.6 Pregnancy and lactation

Pregnancy

There are limited amount of data from the use of this vaccine in pregnant women. Animal studies are insufficient with respect to reproductive toxicity. However, as with all inactivated viral vaccines, the risks to the fetus are considered negligible. 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. Lactation: The vaccine should be used with caution for lactating women. A decision must be made whether to discontinue breast-feeding or to abstain

from vaccination taking into account the benefit of breast feeding for the child and the benefit of vaccination for the woman.

Fertility

No fertility data are available.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable 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.

4.9 Overdose

Not applicable

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Vaccine, Hepatitis A vaccine

Hepatitis A vaccine confers immunization against HAV by stimulating specific immune responses evidenced by the induction of antibodies against HAV.

5.2 Pharmacokinetic properties

Not applicable to vaccine products.

5.3 Preclinical safety data

Not applicable to vaccine products.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium Hydroxide

Sodium dihydrogen Phosphate

Disodium Hydrogen Phosphate

Diluent: solution of sodium chloride

Water for injections

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

3 years from the date of manufacturer when stored at 2 – 8 °C.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

Colorless glass vial with grey Bromobutyl rubber stoppers and aluminium overcaps fitted with Royal blue flip-off tops containing 1 ml of suspension

Colorless glass vial with grey Bromobutyl rubber stoppers and aluminium overcaps fitted with Royal blue flip-off tops containing 0.5 ml of suspension.

6.6 Special precautions for disposal and other handling

- The vaccine should never be administered intravenously.
- The vaccine should be inspected visually for any foreign particulate matter and/or variation of physical aspect prior to administration.
- Before use, the vaccine should be well shaken to obtain a slightly opaque white suspension.
- Discard the vaccine if the content appears otherwise.
- Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorisation holder

Incepta VaccineLtd., Bara Rangamatia, Zirabo, Ashulia, Savar, Dhaka, Bangladesh

8. Drug authorisation number(s)

PreveHAV 1 ml (Adult)- 363-25-069

PreveHAV 0.5 ml (Pediatric)- 363-26-069

9. Date of first authorisation/renewal of the authorization

February 2017

10. DATE OF REVISION OF THE TEXT

May, 2021