1.2.5.10. Summary characteristic _ Annex C

1. NAME OF THE MEDICINAL PRODUCT.

Hepatitis A (Live) Vaccine, Freeze-dried.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Name	Strength
1. Live attenuated Hepatitis A virus.	Not less than 6.50 lgCCID$_{50}$/ml
2. Trehalose.	21 mg
3. Sodium glutamate	3.5.mg
4. Arginine	0.7 mg
5. Urea	2.1 mg
6. Vitamin C	0.7 mg
7. Dextran 40	35 mg
8. Sorbitol	2.1 mg
9. Mannitol	2.1 mg

3. PHARMACEUTICAL FORM

Hepatitis A (Live) vaccine, Freeze- dried.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

The product can induce immunity against hepatitis A virus in recipients following immunization. It is used to prevent Hepatitis A.

4.2 Posology and method of administration

The immune procedure of this product is one dose in full immunization. Reconstitute the vaccine with 1.0ml sterile water for injection. Shake the container till the content is reconstituted completely before use. Inject s.c. a single human dose of the reconstituted vaccine at deltoid insertion area of the lateral upper arm.

The eligibles are Hepatitis A-susceptible healthy children in 1 to 12 years of age.

4.3 Contraindications

(1) Subjects with known allergic reaction to some components of the vaccine, including subsidiary materials and Kanamycin sulfate, chloroform and bovine serum.

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(2) Pregnant woman.

(3) Subjects with acute diseases, severe chronic diseases, and chronic diseases at acute attack stage or fever.

(4) Subjects with immunodeficiency, immuno-compromised subjects or those receiving immunosuppressive therapy.

(5) Subjects with uncontrolled epilepsy or other progressive diseases of nervous system.

4.4 Special warnings and precautions for use

(1) The vaccine shall be administered with caution to the subjects with family or individual history of convulsion and those with chronic diseases, history of epilepsy, allergic diathesis, as well as women during lactation.

(2) Do not use the vaccine if container shows abnormalities, such as crack, illegible label, exceeding expiry date, or the content is abnormal or not transparent after reconstitution.

(3) Care should be taken to avoid contacting the vaccine by disinfectant during opening the container and in the course of injection.

(4) The vaccine shall be administered immediately after the container is opened, or kept at 2-8℃ and used up within 1 hour.

(5) Adrenaline should be available for first aid in case of severe anaphylactic reactions. The recipients shall be observed for at least 30minutes on site following injection.

(6) The immunization with this vaccine should be deferred for at least 3 months following administration of immunoglobulin to avoid the influence on immune effect.

(7) The vaccine should not be given less than one month before or after administration of other live attenuated vaccines.

(8) As a live attenuated vaccine, the product is not recommended to be administered in the epidemic seasons of hepatitis A .

(9) Women of childbearing age should avoid pregnancy for at least 3 months after immunization.

(10) Freezing is strictly forbidden.

4.5 Interaction with other medicinal products and other forms of interaction

Refer to the section 4.3 and 4.4.

4.6 Pregnancy and lactation

Refer to the section 4.3 and 4.4.

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4.7 Effects on ability to drive and use machines

N/A

4.8 Undesirable effects

Common adverse reactions

(1) Pain and tenderness may occur at the injection site generally within 24 hours after vaccination, which can be relieved spontaneously within 2-3 days in most cases.

(2) Transient fever may occur generally within 1-2weeks after vaccination, most of which are mild and can be relieved spontaneously within 1-2days and need no particular treatment. If necessary, the recipients should have an appropriate rest and drink more hot water. Care should be taken to keep warm for the prevention of secondary infections. The recipients with moderate fever or with the fever lasting for more than 48hours may receive physical therapy or symptomatic treatment.

(3) Occasionally, sporadic rash may occur after vaccination and commonly no particular treatment is needed. In case of necessity, symptomatic treatment might be helpful.

Rare adverse reactions:

Severe fever: Physical therapy and symptomatic treatment shall be adopted to prevent febrile convulsion.

Extremely rare adverse reactions:

(1) Anaphylactic shock: Anaphylactic shock may occur within one hour after vaccination, emergency measures shall be adopted immediately including prompt injection of adrenaline.

(2) Allergic rash: Urticaria may occur generally within 72 hours after vaccination, if it occurs the recipients shall go to the clinic promptly and receive anti-anaphylactic treatment.

(3) Allergic purpura: The recipients with allergic purpura shall go to the clinic promptly and receive anti-anaphylactic treatment with corticosteroid. If the treatment is inappropriate or delayed, purpuric nephritis may be complicated.

4.9 Overdose

N/A

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

N/A

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5.2 Pharmacokinetic properties

N/A

5.3 Preclinical safety data

Refer to module 4 and module 5.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Name
Trehalose
Sodium glutamate
Arginine
Urea
Vitamin C
Dextran 40
Sorbitol
Mannitol

6.2 Incompatibilities

The excipient of Hepatitis A (Live) Vaccine, Freeze-dried includes: trehalose, sodium glutamate, arginine, urea, vitamin C, dextran 40, sorbitol and mannitol. The protective reagent is the preservative of freezing and drying process. In preservative, trehalose has a relatively higher transition temperature for glass, with less hydrogen bond, which is helpful to form hydrogen bonds between protein molecules. During freezing and drying processes, it will prevent degeneration of active components. The polysaccharide, including dextran, can improve glass transition temperature of products, and prevent protein damage induced by product collapse. The sterile filtrate of mannitol is stable, cannot be easily oxidized, can provide supporting structure, and will not react with active components. Sorbitol is the isomer of mannitol, but with greater solubility. It is a viscous transparent liquid at normal temperature, with optical rotation, slight sweet taste, and moisture absorption. It is unstable at high temperature, and is used as filling agents in the freezing and drying formula. Amino acid is the best bulking agent. Ascorbic acid is used as the antioxidant, to prevent oxidization and degeneration of freeze-dried sample. The components of the preservative are determined by a large number of experiments on freeze-dried preservatives. It has good compatibility and proper proportions, and protective effects against hepatitis A virus as confirmed in practice. Its virus titer will be not less than 6.50 lgCCID$_{50}$/ml after freeze-dried.

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6.3 Shelf life

18 months

6.4 Special precautions for storage

Store and ship the product at 2-8℃, protected from light.

6.5 Nature and contents of container

Container	Materials
Vial	Injection vial composed of neutral borosilicate glass.
Cap	Aluminum-plastic combination cap.
Plug	Halogenated butyl rubber plug.

6.6 Special precautions for disposal

Refer to the section 4.4.

7. MARKETING AUTHORISATION PREQUALIFICATION> HOLDER

Name and address: Sinopharm India Pvt. Ltd.

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Telephone No. +91-11-45793024

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8. MARKETING AUTHORISATION NUMBER(S)

F. No.: BIO/IMP/19/000045

SINOPHARM INDIA PRIVATE LIMITED NEW DELHI

9. DATE OF FIRST < AUTHORISATION> / RENEWAL OF THE < AUTHORISATION>

03. SEPTEMBER. 2020.

NAME: MR. LIAO CHUANKUN

DESIGNATION: DIRECTOR.

PLACE: INDIA

For Sinopharm India Private Limited
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