

Registration No.: 1C 108/50 (NC)

Importer / Manufacturer: Biogenetech Co., Ltd. / Chengdu Institute of Biological Products Co.,Ltd.

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICAL PRODUCT

CD.JEVAX[®] (Inj.)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

A human dose of 0.5 ml contains:

Live-attenuated JE virus (Seed strain: SA14-14-2)	5.4 log PFU or above
Gelatin	4.8 mg or less
Sucrose	21 mg or less
Lactose	21 mg or less
Urea	2.4 mg or less
Human Serum Albumin	3.0 mg or less
Sterile Diluent (water for injection)	0.5 ml

3. PHARMACEUTICAL FORM

CD.JEVAX[®], Japanese Encephalitis Vaccine, live is a sterile, lyophilized vaccine for subcutaneous use, prepared by passaging Japanese encephalitis (JE) virus, strain SA14-14-2 in monolayer of primary hamster kidney cell culture.

The product looks like a light yellow or light pink crisp cake. After reconstitution, it shall turn into a clear, orange-red or light pink liquid.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Prophylactic immunization against Japanese Encephalitis.

4.2 Posology and method of administration

Posology

Primary immunization for persons at least 9 months of age and older, a single dose of 0.5 ml subcutaneously, and a booster dose can be given from 3 months to 1 year after primary dose.

Method of administration

- After reconstitution with the diluents (water for injection), the vaccine should be used within 1 hour.
- The deltoid muscle of right or left arm is the recommended site of injection. The skin at the site of injection first should be disinfected with alcohol or iodine tincture and allowed to dry thoroughly before injection.
- The vaccine should not be injected into a blood vessel.
- Vaccine recipients should be monitored during and after receiving CD.JEVAX[®] and if any reactions (fever, convulsion etc.) are observed a health care provider should be contacted.
- As for any vaccine, adequate treatment provision, including epinephrine, should be available for immediate use in case an anaphylactic reaction occur.

4.3 Contraindication

- Persons with a proven or suspected history of hypersensitivity/anaphylactic reaction to any component of the vaccine, including gelatin
- Persons with fever, acute infectious disease, tympanitis or active untreated tuberculosis
- Persons with malnutrition, general allergy and convulsion
- Persons with cardiac, liver or kidney troubles
- Persons undergoing any type of immunosuppressive therapy
- Persons with a weak or not proper functioning immune system

4.4 Special warnings and precautions for use

- Prior to injection the health care provider should question the vaccinee or his/her parent, or guardian on his/her recent medical history.
- Remove plastic tab of flip-off cap. Do not remove the rubber stopper. Cleanse stopper with a suitable disinfectant. Reconstitute only with the diluent (water for injection). Shake vial thoroughly.
- The vaccine should be inspected visually for extraneous particulate matter and/or discoloration prior to administration whenever solution and container permit. If either of these conditions exists, the vaccine should not be administered.
- The vaccine should be reconstituted just before use and not be frozen or stored again after reconstitution.

4.5 Interaction with other medical products and forms of interaction

- Although no interactions are known with other medication, the health care provider should question the vaccinee, parent or guardian on recent or current medication usage.
- Currently no clinical data is available of administration of CD.JEVAX[®] at the same time with any other vaccine.
However it is advisable to observe a period of at least 2 to 4 weeks when given prior or after to CD.JEVAX[®].

4.6 Pregnancy and lactation

Do not administer CD.JEVAX[®] during pregnancy or lactation.

4.7 Effects on the ability to drive and use machines

N/A

4.8 Undesirable effects

- As is the case for all medications, also the administration of CD.JEVAX[®] can cause adverse reactions.
- Clinical reactions are observed in a small percentage of the vaccinees after administration of CD.JEVAX[®].
- Some events as below have been reported after injection, which normally does not last longer than 2 days, mostly relieved spontaneously; commonly no particular treatment is required, in case of necessity, symptomatic treatment might be recommended.
 - Fever (Increase temperature above 37.5°C)
 - Rash and Nausea
 - Local redness, pain or sensitivity
 - Crying, lost of appetite, sleepiness or sleep problems (children)

4.9 Overdose

N/A

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

N/A

5.2 Pharmacokinetic properties

N/A

5.3 Preclinical safety data

N/A

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Gelatin, Sucrose, Lactose, Urea, Human Serum Albumin, Sterile Diluent (Water for injection)

6.2 Incompatibilities

N/A

6.3 Shelf life

24 months from the date of manufacture.

6.4 Special precautions for storage

The vaccine should be stored and shipped at 2-8°C, protected from light. The diluents should be stored at between 2~30°C.

6.5 Nature and contents of container

Vial, single dose (10 per package) with/without vial or ampoule of diluents (10 per package, each 0.5 ml)

6.6 Special precautions for disposal and other handling

N/A

7. MARKETING AUTHORISATION HOLDER

Biogenetech Co., Ltd.

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8. MARKETING AUTHORISATION NUMBER(S)

1C 108/50 (NC)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

August 16, 2007

10. DATE OF REVISION OF THE TEXT

January 6, 2021