BORUNG
Japanese Encephalitis Vaccine
Inactivated Japanese Encephalitis virus

BORUNG Japanese Encephalitis Vaccine is a sterile liquid of purified Japanese encephalitis virus, obtaining from the brain of the mice inoculated intracerebrally with Nakayama strain.

COMPOSITION
Each 1mL contains,
Active
 Inactivated Japanese encephalitis virus 1mL
Ingredient of suspension
Buffer
Dibasic sodium phosphate 2.51mg
Potassium dibydrogen phosphate 0.408mg
Isotonic agent
Sodium chloride 8.3mg
Surfactant
Polysorbate 80 0.2mg
Stabilizer
Disodium edetate 0.04mg
Preservative
Thimerosal 0.04mg
Solvent
Water for injection q.s.

INDICATIONS:
Prevention from Japanese encephalitis

APPEARANCE
Colorless clear or slightly whitish turbid liquid containing inactivated Japanese encephalitis virus

DOSAGE & ADMINISTRATION:
Subcutaneous injection
Primary immunization:
Two doses of 1mL at the interval of 1~2 week, the third dose of 1mL is given after 12 months. (Inject each dose of 0.5mL for the children below 3 years.)
Booster doses: One dose of 1mL at each 6 and 12 years of age.

PRECAUTIONS
1. Contraindications
Examine vaccines by asking and seeing, and if necessary, by auscultation and percussion. Then, vaccination is prohibited when vaccines are judged as one of the following cases. But vaccination can be performed in case that there is a danger of infection with Japanese encephalitis virus and no possibility to cause significant disorder by vaccination.
1) Febrile patient or the person with malnutrition
2) Person with acute, or gradually serious or active cardiovascular, kidney and liver disease
3) Person who may manifestly develop allergy by the components of the vaccine
4) Person who showed adverse reaction following the injection of this vaccine before
5) Person who showed the symptom of spasm within 1 year before vaccination
6) Pregnant women
7) Person whose state is not enough to be vaccinated besides the above cases
8) Person who have the hypersensitivity to thimerosal.
2. Adverse reaction
1) There is the possibility of local reaction such as erythema, abscess, sharp pain and nodule formation, systemic reaction such as fever, rigor, headache, fatigue, and rarely diarrhea, dizziness, arthralgia, eruption, vomiting, stomachache. But usually they disappear within 2~3 days.
2) Hypersensitivity can be occurred because this drug contains thimerosal (organic forms of mercury).
3. General Caution
1) Prior to injection, ought to confirm that there are some turbid, coloration, mixture of an extraneous substance and etc. If there are, do not use.
2) Advise the vaccinees or their guardians that the vaccines should keep equilibrium, the injection site is kept clean, and the symptoms of high fever, spasm is reported to doctor as soon as they happen.

3) Epinephrine Injection (1:1,000) must be immediately available should an anaphylactic or other allergic reaction occur due to any component of the vaccine.

4) Generalized urticaria or vascular edema are able to occur in several minutes after vaccination or up to 17 days, and the principle reaction occur within 2-10 days.

5) Watch for 30 minutes after vaccination and the reaction have been characterized by urticaria, often in a generalized distribution, or an angioedema of the extremities, face especially lips and oropharynx.

4. Precaution for Pediatric Use

Safety and efficacy in infant under one year of age have not been established.

5. Caution in Use

1) Vaccination apparatus is used after sterilizing by dry heat, high pressure stream, boiling, ethylene oxide gas or gamma ray emitted from Cobalt 60 and then, cooling to room temperature. If possible, avoid sterilizing by boiling.

2) Necessary volume is sucked into syringe after sterilizing stopper and its surrounding with ethanol. During this procedure, care must be taken to avoid bacterial contamination into the drug solution. Furthermore, transfer the drug solution to other container for use is prohibited.

3) At the time of administration, shake well to make homogeneous suspension and use immediately.

4) The injection site is usually upper arm lateral and disinfected with ethanol or tincture of iodine. And repeated injections at the same site should be avoided.

5) Confirm the tip of needle should not penetrate blood vessel.

6) Needle should be changed to each vaccine.

6. Cautions in Handling

1) Do not use frozen vaccine for fear of quality change.

2) Make the refrigerated vaccine room temperature and homogeneous by shaking before use.

3) The vial punctuated once should be used on the day.

STORAGE CONDITION

Keep refrigerated at 2-8. Do not freeze. Every package and label shows an expiry date.

HOW TO SUPPLIED

1mL × 10 Vials

250-3 Jukhyeon-ri, Kwanghyeong-myeon, Jincheon-gun, Chungcheongbuk-do, Korea