SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICAL PRODUCT
JAPANESE ENCEPHALITIS VACCINE-GCC INJ.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
1 mL contains
- Inactivated Japanese Encephalitis Virus suspension (Nakayama strain) 1 mL
- Potassium Phosphate, monobasic (buffer) q.s.
- Sodium Phosphate, dibasic (buffer) q.s.
- Sodium Chloride (isotonic agent) q.s.
- Purified Gelatin (stabilizer) q.s.
- Polysorbate 80 (stabilizer) q.s.
- Thimerosal (preservative) 0.0015 w/v%
- Water for Injection q.s.

3. PHARMACEUTICAL FORM
Japanese Encephalitis Virus is propagated to individuals through pigs or mosquitoes and develops lesions in cerebral cortex or cerebellum, etc. And in severe cases, it often develops paralysis, coma, and insanity.

Japanese Encephalitis Vaccine is a colorless or whitish turbid suspension containing inactivated Japanese Encephalitis Virus and also contains thimerosal as a preservative. Japanese Encephalitis Virus is purified from brains of suckling of mice which have been artificially infected with Nakayama strain, and inactivated by formalin.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
For the prevention of Japanese Encephalitis

4.2 Posology and method of administration
1) Inject subcutaneously
2) The recommended primary immunization series are as follows,
   - Three doses of 1.0 mL each for individuals to be given on days 0, 7 and 28 or
   - Two doses of 1.0 mL each for individuals to be given at intervals of 1~4 weeks.
3) A booster dose of 1.0 mL may be given 1 year after the primary immunization.
   The additional booster doses of 1.0 mL each may be given every 3 years after the first booster dose.
   (For children under 3 years of age, each 0.5 mL/dose may be given in the same manner)

4.3 Contraindication
Individuals who meet the criteria presented below should not be administered. But individuals with no care of predictable significant disorders caused by immunization in high risk groups should be given.
1) Fever or severe dystrophy
2) Cardiovascular diseases, renal diseases or hepatic diseases with acute phase or active phase
3) Hypersensitivity to any component of the vaccine
4) Individuals who may develop abnormal adverse reactions to the vaccine
5) Individuals who have experienced convulsions within 1 year prior to vaccination
6) Pregnant women
7) Individuals whose healthy conditions are not suitable for vaccination
8) Individuals who are oversensitive to thimerosal

4.4 Special warnings and precautions for use
1) Once frozen, do not use it.
2) Keep at room temperature after taking from refrigerator and shake well before use.
3) A needle should not be entered into blood.
4) Once used, the needle should not be used again for another vaccination.

4.5 Interaction with other medical products and forms of interaction
N/A

4.6 Pregnancy and lactation
The vaccine is contraindicated in pregnant women.

4.7 Effects on the ability to drive and use machines
N/A

4.8 Undesirable effects
The following adverse reactions may occur, but generally disappear within 2 or 3 days.
Local redness, swelling, pain, fever, chills, headache, and lassitude, etc.

4.9 Overdose
N/A

5 PHARMACOLOGICAL PROPERTIES

5.4 Pharmacodynamic properties
N/A

5.5 Pharmacokinetic properties
N/A

5.6 Preclinical safety data
N/A

6 PHARMACEUTICAL PARTICULARS

6.4 List of excipients
Potassium Phosphate (monobasic), Sodium Phosphate (dibasic), Sodium Chloride, Polysorbate 80, Purified gelatin, Thimerosal, Water for injection

6.5 Incompatibilities
N/A

6.6 Shelf life
Maximum validity: 18 months from the date of manufacture.
6.7 Special precautions for storage
Store at 2-8°C. Do not freeze.

6.8 Nature and contents of container
1 ml/vial

6.9 Special precautions for disposal and other handling
N/A

7 MARKETING AUTHORISATION HOLDER
Biogenetech Co., Ltd.
18 Soi Udomsuk 37, Sukhumvit 103 Rd., Bangjak, Prakanong, Bangkok, 10260 THAILAND

8 MARKETING AUTHORISATION NUMBER(S)
1C 70/50

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