SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICAL PRODUCT

J.E. (BEIJING) – GPO

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of vaccine contains :
- Inactivated JE Virus ≥ Antigen content of reference vaccine
- Gelatin 0.02 %
- Tween 80 0.0003 %
- Thimerosal 0.009 %
- M 199 (without phenol red) qs 1 ml

3. PHARMACEUTICAL FORM

Colorless, transparent or slightly whitish turbid liquid for injection filled in a glass vial with butyl rubber stopper and aluminium cap.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Immunization against Japanese encephalitis

4.2 Posology and method of administration

1. For initial immunization, two shots of 0.5 ml each are administered subcutaneously at an interval of 1-2 weeks. To those who are over 60 years of age or to those who intend to step into highly endemic areas of Japanese encephalitis for the first time. One more shot of 0.5 ml is recommended one month after the two initial doses in order to strengthen immune effect.

2. For boosting immunization another dose of 0.5 ml is administered subcutaneously every 1-3 years in order to maintain the immunity.

Note: For children under 3 years of age the dose should be decreased to a 0.25 ml for each administration.
4.3 Contraindication

Individuals with the following conditions or diseases, except when in the opinion of physicians, withholding the vaccine entails even greater risk.
1. High fever or severe infection.
2. Cardiovascular, renal or hepatic diseases.
3. Diabetes or severe malnutrition.
4. History of convulsion or spasmodic symptoms within one year before vaccination.
5. Leukemia, lymphoma, and cancer in exacerbating phase.
6. History of hypersensitivity to components of the vaccine.
7. Pregnancy.

4.4 Special warnings and precautions for use

1. Do not use when the vaccine is frozen.
2. Shake before administration.
3. Use of a disposable syring and needle is recommended in order to avoid transmission of infectious agents from one to another.

4.5 Interaction with other medical products and forms of interaction

Immunosuppressants.

4.6 Pregnancy and lactation

Contraindication.

4.7 Effects on the ability to drive and use machines

The Vaccine is unlikely to produce an effect on the ability to drive and use machines.

4.8 Undesirable effects

Local reactions such as redness, swelling, tenderness, etc. or systematic reactions such as fever, chill, headache, etc. may occur.

4.9 Overdose

Overdose of vaccine will not cause anymore severe undesirable effects.

5. Pharmacological Properties

Pharmacotherapeutic group: Japanese Encephalitis vaccine
ATC code: J>Ag

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, TWEEN 80, Thimerosal, M199 (without phenol red)

6.2 Incompatibilities  
There is no report of incompatibility. The vaccine should not be mixed with other for administered.

6.3 Shelf life  
According to the label of vaccine when stored in stated condition

6.4 Special precautions for storage  
Store the vaccine at 2-8 °C and do not freeze. Exposure of the vaccine to direct sunlight should be avoided.

6.5 Nature and contents of container  
Vaccine is filled in a transparent type I glass vial with butyl rubber stopper and aluminium cap.

6.6 Special precautions for disposal and other handling  
Exposure of the vaccine to direct sunlight should be avoid

7. MARKETING AUTHORISATION HOLDER  
The Government Pharmaceutical Organization

8. MARKETING AUTHORISATION NUMBER(S)  
1A 176/45

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION  
22 May 2002

10. DATE OF REVISION OF THE TEXT  
7 February 2011