Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

1.1 Product Name

JEVAC™ Chromatographically Purified Vero Cell
Inactivated Japanese Encephalitis Vaccine (Beijing P3 Strain)

1.2 Strength

0.5ml/vial

1.3 Pharmaceutical Dosage Form

Freeze-dried powder

2. QUALITY AND QUANTITATIVE COMPOSITION

2.1 Qualitative Declaration

1 dose (0.5ml) of JEVAC™ contains:

Inactivated Japanese Encephalitis Virus (P3 strain propagated on Vero cell and inactivated with β-propiolactone), for a full list of excipients, see section 6.1.

2.2 Quantitative Declaration

Inactivated Japanese Encephalitis Virus (P3 strain propagated on Vero cell and inactivated with β-propiolactone), the corresponding potency shall be no less than that of the reference vaccine (Chinese NICPBP reference vaccine).

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Injection, Freeze-dried powder

4. CLINICAL PARTICULARS

4.1 Therapeutic indication

Prophylactic immunization against Japanese Encephalitis

4.2 Posology and method of administration

- The vaccine should be administrated by subcutaneously or intramuscularly.

- Primary immunization for children of 6 months of age and those including children and adults, who intend to enter the endemic area, 0.5ml dose is administered twice at an interval of 7-28 days.

- Booster immunization shall be administered from 1 year after the primary dose.
4.3 Contraindication
- Hypersensitivity to any component of the vaccine.
- Fever, cardiovascular, renal or hepatic diseases in acute, aggravating or active phase.
- Brain disease, uncontrolled epilepsy and other progressive psychosis.

4.4 Special warning and precautions for use
- Don’t inject by the intravascular route.
- Before use, please check whether the container, label and expiry date are qualified.
- Don’t use the vaccine if any turbidity or colour change of content, foreign matters or leakage of container is found.
- The recipients shall take a rest for a while on site following immunization. Adrenaline should be available for first aid in case of severe anaphylactic reactions.
- The vaccine should be reconstituted just before use and not be frozen or stored again after reconstitution.

4.5 Interaction with other medicinal products and other forms of interactions
- 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 JEVAC 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 to or after JEVAC.

4.6 Pregnancy and lactation
If the JE risk is sufficient to warrant vaccination of pregnant women, inactivated Vero cell-derived vaccines should be used preferentially over live attenuated or live recombinant vaccines based on the general precautionary principle against using live vaccines in pregnant women especially if alternative types of vaccines are available. Pregnancy testing is not a prerequisite for JE vaccination. Inadvertent administration of live attenuated or live recombinant JE vaccine to a pregnant women is not an indication for termination of the pregnancy.

4.7 Effects on ability to drive and use machine
No studies on the effect of JEVAC on the ability to drive and use machines have been performed.

4.8 Undesirable effects
Like all medicine, JEVAC can cause side effects, although not everybody gets them. The following side effects could found with the use of JEVAC.
Local reaction: Pain, inch, erythema, edema and induration at the injection site.
Systemic reaction: Some individuals may feel dizziness, have transient fever reaction and skin rashes, which normally does not last longer than 48 hours, if the person who has the fever exceed 38.5°C or longer than 48 hours, please consult the doctors.

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 excipient
Dextran 40, Human Serum Albumin, Phosphate Buffered Saline (Sodium chloride, Sodium dihydrogen phosphate and disodium hydrogen phosphate), Water for injection

6.2 Incompatibilities
N/A

6.3 Shelf life
24 months.

6.4 Special precautions for storage
Store and ship at 2-8°C. Do not freeze. Protect from light.

6.5 Nature and contents of container
Vial, single dose (1 per package) with ampoule of diluent (1 per package, each 0.5ml).

7. MARKETING AUTHORIZATION HOLDER
Biovalys Co., Ltd. Bangkok, Thailand.

8. MARKETING AUTHORIZATION NUMBERS
1C 31/57 (NB)

9. DATE OF AUTHORIZATION
July 12, 2017

10. DATE OF REVISION OF THE TEXT
May 9, 2018