SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICAL PRODUCT

Inactivated Japanese Encephalitis Vaccine for Human Use (Vero cell), Freeze-Dried Final Bulk

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (0.5 ml) of vaccine bulk contains:
Inactivated Japanese Encephalitis Virus (Beijing 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).

3. PHARMACEUTICAL FORM

Suspension for intramuscular injection

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Prophylactic immunization against Japanese Encephalitis

4.2 Posology and method of administration

Administration

As Vaccine bulk/ready to fill is intended to further manufacturing step from filling, lyophilized until it becomes to Inactivated Japanese Encephalitis Vaccine for Human Use (Vero cell), Freeze-Dried.

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 warnings 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 medical products and forms of interaction

N/A

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 woman is not an indication for termination of the pregnancy.

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

4.8 Undesirable effects
Like all medicines, TRCS JEVAC can cause side effects, although not everybody gets them. The following side effects could found with the use of TRCS JEVAC.
Local reaction: Pain, itch, 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 excipients
Human Serum Albumin and Dextran 40

6.2 Incompatibilities
N/A

6.3 Shelf life
3 months

6.4 Special precautions for storage
Store between 2 – 8 °C. DO NOT FREEZE. Protect from light.

6.5 Nature and contents of container
5 liter to 20 liter of HyQtainer Bioprocess Container

6.6 Special precautions for disposal and other handling
N/A

7. MARKETING AUTHORISATION HOLDER
BioNet-Asia Co.,Ltd.
Bangkok, THAILAND

8. MARKETING AUTHORISATION NUMBER(S)
1C 12/62 (NBC)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

16 December 2019

10. DATE OF REVISION OF THE TEXT