Japanese Encephalitis Vaccine
Inactivated (Adsorbed, Human) IP
(Vero cell derived)

1. NAME AND DESCRIPTION OF THE MEDICINAL PRODUCT:
JENVAC® is a suspension for injection presented in liquid formulation and is intended for human use, for prevention of clinically and mortally encephalitic cases of Japanese Encephalitis. It is a basic preparation containing the JE virus strain KUNI-65-22 isolated from an epidemic outbreak of JE in Japan. The vaccine is prepared by purification and inactivation processes consistent with current good manufacturing practice. The vaccine fulfills WHO requirements for Purified Inactivated Japanese Encephalitis Vaccine.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:
Each 0.5 mL contains:
- Purified inactivated Japanese Encephalitis Vaccine Protein (JE Virus strain KUNI-65-22) 0.96 mg
- Aluminum Hydroxide Gel 0.25 mg
- Thiomersal (EthylMercaptobutylsulphate) 0.025 mg
- Preservative (30 mg of phenol and 5 mg of Boric acid) 0.05 mg

3. PHARMACOLOGICAL FORM:
Suspension for injection.

4. CLINICAL PARTICULARS:
4.1 Pharmacodynamic and Pharmacokinetic:
JENVAC® is indicated for active immunization against Japanese Encephalitis infection in adults and children aged one year and above. It should be used in children and adults at risk of exposure through travel to JE endemic areas, spending a month or longer in endemic areas during the transmission season for the course of their occupation or residing in areas where JE virus is endemic.

4.2 Posology and method of administration:
JENVAC® is administered intramuscularly by the deltoid region of upper arm for adults and upper arm or thigh for children. Do not administer intradermally, subcutaneously or intravenously.

4.3 Dose and schedule:
The primary vaccination consists of a single dose of 0.5 mL. If the vaccine was administered more than 1 year ago, an additional dose may be given to prevent re-infection or re-exposure to endemic area.

4.4 Contraindications:
Vaccine should not be given to individuals with known or suspected hypersensitivity to the vaccine.

4.5 Special warning/precaution:
- Vaccine must not be given to individuals with known or suspected hypersensitivity to the vaccine.

4.6 Interaction with other medicinal products and other forms of interaction:
- For concomitant administration of other injectable product, use different injection sites.

4.7 Special precautions for use:
- Vaccine should not be mixed with other drugs.

4.8 Effect on the ability to drive and use machines:
Safety and efficacy have not been established in pregnant women and in nursing mothers.

4.9 Undesirable effects:
The safety of JENVAC® vaccine was established in controlled clinical trials in healthy volunteers in comparison with a licensed JE vaccine. General adverse events such as fever, headache, body aches and local adverse events such as pain, redness and swelling at the injection site were the frequently reported adverse events after administration of JENVAC®.

5. PHARMACOLOGICAL PROPERTIES:
5.1 Pharmacodynamic properties:
Pharmacodynamics of JENVAC® vaccine were studied using mouse models for Japanese Encephalitis infection. The vaccine was found to be effective in preventing the development of encephalitis.

5.2 Pharmacokinetic properties:
The vaccine is rapidly absorbed following intramuscular administration.

6. CLINICAL STUDIES:
In a phase I study, the safety and immunogenicity of BBIL’s JENVAC® vaccine was established in healthy subjects administered at the development protocol by an IRB study. The phase II study demonstrated a single dose of JENVAC® vaccine was able to induce an immune response and to protect against infection.

5.3 Pre-clinical safety study:
The vaccine was administered in the mouse model and was found to be safe.

5.4 Preclinical studies:
The vaccine was found to be safe and effective in the mouse model.

6. PHARMACOLOGICAL PROPERTIES:
6.1 List of excipients:
- Phosphate buffered saline
- Aluminum Hydroxide Gel
- Thiomersal

6.2 Incompatibilities:
This medicinal product should not be mixed with other medicinal products.

6.3 Shelf life:
The expiry date of the vaccine is indicated on the label and should be in excess of 24 months.

6.4 Special precautions for storage:
- Store at +2 to +8°C.
- Protect from light.

6.5 Method of disposal:
Do not allow the vaccine to enter drains or sewage systems.

7. MARKETING INFORMATION:
7.1 Administration:
This medicinal product must not be mixed with other medicinal products.

7.2 Incompatibilities:
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7.4 Special precautions for storage:
- Store at +2 to +8°C.
- Protect from light.

7.5 Method of disposal:
Do not allow the vaccine to enter drains or sewage systems.

7.6 Rescue equipment:
In case of anaphylaxis, epinephrine should be immediately available for treatment of any anaphylactic reactions that may occur during administration.

7.7 Special storage requirements:
This medicinal product must be stored at room temperature before administration.

7.8 Exposure of human and domestic animals to the vaccine:
This medicinal product should not be mixed with other medicinal products.

7.9 Special precautions for disposal of unused medicinal products:
This medicinal product should not be mixed with other medicinal products.

7.10 Special precautions for disposal of waste from medicinal products containing hazardous substances:
This medicinal product should not be mixed with other medicinal products.

8. OVERDOSAGE:
In case of anaphylaxis, epinephrine should be immediately available for treatment of any anaphylactic reactions that may occur during administration.

9. INTERACTIVE EFFECTS:
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