What is JEEV®?

JEEV® is a vaccine with the following composition:

<table>
<thead>
<tr>
<th>Components</th>
<th>Quantity /dose(0.5 mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purified Inactivated Japanese Encephalitis Virus Strain (SA14-14-2)</td>
<td>6 µg</td>
</tr>
<tr>
<td>Aluminium as Aluminium Hydroxide</td>
<td>0.1% w/v</td>
</tr>
<tr>
<td>Phosphate Buffer Saline</td>
<td>q.s</td>
</tr>
</tbody>
</table>

Container

JE vaccine is dispensed into 3 mL USP Type I clear tubular glass vials which are sealed with 13 mm grey bromobutyl rubber stoppers and capped with scarlet red coloured aluminium flip-off seals.

Real time and accelerated stability reviewed supports the use of a VVM type 7. The VVM is attached to the flip off cap.

Inactivated Bulk manufacture and Formulation occurs in the facility at Azamabad, India
-Filling of the final product occur in the Production Plant at Shameerpet, India

What is JEEV® used for?

JEEV® is indicated for active immunization against Japanese Encephalitis Virus. The age range approved for WHO prequalification is 18 years to 49 years. For information about JEEV® in other age ranges, please see the section below: Other information about evaluation of JEEV®

How is JEEV® used?

The primary immunization course of JEEV® is administration of two doses of 6µg / 0.5ml each with the second dose administered 28 days after the first dose.

The vaccine is administered intramuscularly. The preferred location is the deltoid muscle of upper arm for adults.

There is no data regarding co-administration of JEEV® with other vaccines.
What are the vaccine characteristics?

JEEV® must be stored between 2-8°C. It must not be frozen. Under these recommended storage conditions, the vaccine is stable for 24 months from the date of manufacture.

The vaccine does not contain any preservative.

Cold chain volume per dose is 14.7 cm³ in the secondary carton.

Who is the regulatory authority responsible for its oversight vis a vis WHO?

JEEV® was cleared for license in India, its country of manufacture, by CDSCO on 29 September 2011.

How has JEEV® been studied from the clinical point of view?

JEEV® is the result of a technology transfer of inactivated VERO-cell derived purified, adjuvanted IC51 (IXIARO) vaccine, from Intercell. The IC51 (IXIARO) vaccine has been licensed in several countries based on the similar safety and immune profile compared to the inactivated mouse-brain derived vaccine JEVAX, which is known to be effective against JE.

JEEV® has been shown to be safe in a phase I trial, BECT013, with two doses (6 µg/0.5ml) in healthy adults. A phase II/III study, BECT018, was conducted in young children in India; in that study JEEV® was used at 0.3µg/0.25ml in a 2-dose schedule. The limited evidence for immunogenicity and safety currently available for JEEV® was considered sufficient given the acceptance of the degree of similarity between JEEV® and IC51 (IXIARO) in terms of same raw materials (cell banks and virus seed banks), same process flow and compliance of the two vaccines with the same in-process controls and release specifications. A booster dose of IC51 (IXIARO) at month 12 after primary immunization is recommended for adults at continuous risk for acquiring Japanese Encephalitis such as persons residing in endemic areas. By analogy such recommendation may be extended for JEEV®, but this has not been approved by the national regulatory authority of reference.

Other information about evaluation of JEEV®:

As part of the prequalification process for JEEV®, the Product Summary File and the responses provided by manufacturer to observations made by WHO has been reviewed for quality, safety and efficacy by a team of WHO experts, and found to meet WHO requirements of WHO TRS 963, Annex 1. Manufacturer’s manufacturing facility was audited by a WHO team of experts and found to be in compliance with WHO GMP requirements [WHO TRS 822, Annex 3; TRS 961, Annexes 2, 3 and 6].

WHO has conducted independent testing of batches of the vaccine for critical release parameters in contracted laboratories qualified by WHO for the purpose, and results obtained were in compliance with the quality specifications of the product.

The licensed vaccine in India includes an indication for children aged 12-35 months. These recipients receive a dose of 0.25ml. There is currently not a WHO prequalified syringe with an auto-disable feature available to deliver this dose. Pending the
development of such a syringe, the WHO prequalification does not include this indication. However, the clinical data submitted with this application supported the use of the 0.25ml dose in the 12-35 month age group. Clinical studies in support of an indication for 3-17 year olds (0.5ml dose) are on going and the company has indicated its intention to submit a variation supporting immunisation of this age group.

This summary was last updated and published on 24 July 2013