# Public Summary

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| **Summary for ARTG Entry:** | 162215 IMOJEV japanese encephalitis vaccine (live, attenuated) powder for injection vial plus diluent vial |
| **ARTG entry for** | Medicine Registered |
| **Sponsor** | Biocelect Pty Ltd |
| **Postal Address** | Suite 5 02 Level 5, 139 Macquarie street, Sydney, NSW, 2000 Australia |
| **ARTG Start Date** | 23/08/2010 |
| **Product Category** | Medicine |
| **Status** | Active |
| **Approval Area** | Drug Safety Evaluation Branch |

## Conditions

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Conditions Applying to Therapeutic Goods Accepted for Registration or Listing as Goods Currently Supplied at the Commencement of the Therapeutic Goods Act 1989"

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 February 1992, other than condition No. 8 and condition No. 9.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 February 1992, other than condition No. 11.

Except where the sponsor has been contracted by an overseas partry to manufacturer the goods and that party will be responsible for placing the goods on the market in countries other than Australia, the sponsor must have and shall retain, while the goods remain listed, evidence necessary to substantiate and support the accuracy of the indications in relation to the listed goods, and upon the request of the Head, Office of Prescription Medicines Authorisation Branch, Therapeutic Goods Administration, shall produce such evidence to this officer.

The conditions applying to these goods when they are exported from Australia are given below:

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995, other than condition No. 8 and condition No. 9.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995, other than condition No.11

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

The therapeutic goods grouped in this registration/listing as export only goods under the following names are included in the Australian Register of Therapeutic Goods and may not be supplied in Australia. Export Name(s) to be added:

## Products

### 1 . IMOJEV japanese encephalitis vaccine (live, attenuated) powder for injection vial plus diluent vial

**Product Type** Composite Pack **Effective Date** 21/06/2024

**Permitted Indications**

No Permitted Indications included on Record

**Indication Requirements**

No Indication Requirements included on Record

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

IMOJEV is indicated for prophylaxis of Japanese encephalitis caused by the Japanese encephalitis virus, in individuals from 9 months of age and over.

**Warnings**

See Product Information and Consumer Medicine Information for this product

**Additional Product information**

**Container information**

| Type | Material | Life Time | Temperature | Closure | Conditions |
|---|---|---|---|---|---|
| Multiple containers | Glass Type I Clear | 48 Months | Store at 2 to 8 degrees Celsius | Neither child resistant closure nor restricted flow insert | Do not Freeze<br>Protect from Light |

**Pack Size/Poison information**

| Pack Size | Poison Schedule |
|---|---|

**Components**

**1 . Diluent**

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| **Dosage Form** | Diluent, not applicable |
| **Route of Administration** | Subcutaneous |
| **Visual Identification** | Clear solution |

**Other Ingredients (Excipients)**

**sodium chloride**
**water for injections**

**2 . Live, attenuated, recombinant vaccine**

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|---|---|
| **Dosage Form** | Injection, powder for |
| **Route of Administration** | Subcutaneous |
| **Visual Identification** | A white to creamy white homogeneous cake which might be retracted. |

**Active Ingredients**

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|---|---|
| **Japanese encephalitis virus** | **4 PFU** |

**Other Ingredients (Excipients)**

**Albumin**
**glutamic acid**
**histidine**
**lactose monohydrate**
**mannitol**
**potassium hydroxide**
**sodium chloride**
**water for injections**