



IMOJEV®

Powder and diluent* for suspension for injection Japanese encephalitis vaccine (live, attenuated)

* 0.4 % Sterile Sodium chloride solution

NAME AND STRENGTH OF ACTIVE INGREDIENT(S)

Live, attenuated, recombinant Japanese encephalitis virus*: 4.0 - 5.8 log PFU** per dose (0.5 mL)

* Propagated in Vero cells

** Plaque Forming Unit

PRODUCT DESCRIPTION

IMOJEV® is a monovalent, live attenuated viral vaccine.

Active Ingredients:

Live, attenuated, recombinant Japanese encephalitis virus: 4.0 - 5.8 log PFU* per dose (0.5mL)

* Plaque Forming Unit

Excipients:

- Mannitol
- Lactose
- Glutamic acid
- Potassium hydroxide
- Histidine
- Human Serum Albumin
- Sodium chloride
- Water for injections

No adjuvant or antimicrobial preservative is added.

The powder is a white to creamy white homogeneous cake which might be retracted from the sides of the vial. The diluent is a clear sterile solution. After reconstitution, **IMOJEV®** is a colourless to amber suspension.

PHARMACODYNAMIC/PHARMACOKINETICS

Pharmacodynamic properties

Mechanism of action

The vaccine is a live attenuated virus. Following administration, the virus replicates locally and elicits neutralising antibodies and cell-mediated immune responses that are specific to the Japanese encephalitis virus. Available results indicate that protection is mainly mediated by neutralising antibodies.

In nonclinical studies, all animals that received a single dose of the vaccine developed specific neutralising antibodies against Japanese encephalitis virus and were protected against infection by a virulent Japanese encephalitis virus experimental challenge.

A single dose administration of **IMOJEV®** is as immunogenic as a three-dose regimen of an inactivated Japanese encephalitis comparator vaccine administered in adults 18 years of age and over. A seroprotective level of antibodies is generally reached 14 days after vaccination.

In persons 9 months of age and over, a seroprotective level of antibodies is generally reached 28 days after vaccination.

Pharmacokinetic properties:

Not applicable.

INDICATIONS

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

RECOMMENDED DOSE AND MODE OF ADMINISTRATION

Persons 9 months of age and over: one single dose of reconstituted IMOJEV® 0.5 mL injection should be administered for primary immunization.

In children and adolescents up to 18 years of age, if a long term protection* is required, one 0.5 mL dose of **IMOJEV®** should be given as a booster dose after the first vaccination. The booster dose should be given preferably 1 year after the first vaccination and can be given up to 2 years after the first vaccination.

One 0.5 mL dose of **IMOJEV®** can also be given as a booster vaccination in children who were previously given inactivated Japanese encephalitis vaccine for primary vaccination, in accordance with the recommended timing for the booster of the inactivated Japanese encephalitis vaccine.

* Immunity is maintained at a high level at least 4 years after the booster dose regardless the vaccine used for first vaccination.

In adults, there is no need for a booster dose up to 5 years after the administration of a single dose of **IMOJEV®**.

Once the freeze-dried vaccine has been completely reconstituted using the diluent provided (see

section "Instructions for use"), it is administered via the subcutaneous route.

In persons 2 years of age and over, the recommended injection site is the deltoid region of the upper arm.

In persons between 9 and 24 months of age, the recommended injection site is the anterolateral aspect of the thigh or the deltoid region.

Do not administer by intravascular injection.

IMOJEV® must not be mixed with any other injectable vaccine(s) or medicinal product(s).

Contact with disinfectants is to be avoided since they may inactivate the vaccine virus.

Instructions for use

Using aseptic technique, **IMOJEV®** vaccine is reconstituted by injecting all the 0.4 % sodium chloride solution into the vial of freeze-dried vaccine, using the syringe and one of the needles provided in the carton. The vial is gently swirled. After complete dissolution, a 0.5 mL dose of the reconstituted suspension is withdrawn into this same syringe. For injection, the syringe is fitted with the second needle provided in the package. The product should be used once reconstituted.

After use, any remaining vaccine and container must be disposed of safely, preferably by heat inactivation or incineration, according to locally agreed procedures

CONTRAINDICATIONS

IMOJEV® should not be administered to anyone with a history of severe allergic reaction to any component of the vaccine or history of severe allergic reaction after previous administration of the vaccine or a vaccine containing the same components or constituents.

Vaccination must be postponed in case of febrile or acute disease.

Congenital or acquired immune deficiency impairing cellular immunity, including immunosuppressive therapies such as chemotherapy, high doses of systemic corticosteroids given for 14 days or more (see section Warnings and Precautions).

IMOJEV® must not be administered to persons with symptomatic HIV infection or with asymptomatic HIV infection when accompanied by evidence of impaired immune function.

Pregnancy and lactation (see section "Use in Pregnancy"; "Use in Lactation").

WARNING AND PRECAUTIONS

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following administration of the vaccine.

For patients following a treatment with high doses of systemic corticosteroids given for 14 days or more, it is advisable to wait for at least one month or more following the interruption of therapy before carrying out the vaccination until immune function has recovered.

IMOJEV® should under no circumstances be administered intravascularly.

INTERACTIONS WITH OTHER MEDICAMENTS

Interactions

Separate injection sites and separate syringes should be used when other vaccines are concomitantly administered with **IMOJEV®**.

From 12 months of age, **IMOJEV®** may be administered at the same time as vaccines against measles, mumps, or rubella, either stand alone or combined.

For children living in areas where risk for measles is high, **IMOJEV®** may be administered at the same time as measles vaccine, either stand alone or combined with mumps and/or rubella vaccines, from 9 months of age.

IMOJEV® may be administered to adults at the same time as yellow fever vaccine.

In the case of immunosuppressive therapy or corticosteroid therapy, refer to sections "Contraindications" and "Warnings and Precautions".

Administering the vaccine in persons who have previously received immunoglobulins:

In order to avoid any neutralisation of the attenuated viruses contained in the vaccine, vaccination must not be performed within 6 weeks, and preferably not within 3 months of injection of immunoglobulins or blood products containing immunoglobulins, such as blood or plasma.

PREGNANCY AND LACTATION

Use in Pregnancy

Animal studies did not indicate direct or indirect harmful effects with respect to pregnancy, embryo-fetal development, parturition or post-natal development.

As with all live attenuated vaccines, pregnancy constitutes a contra-indication (see section "Contraindications").

Use in Lactation

Animal studies did not indicate direct or indirect harmful effects with respect to lactation. It is not known whether this vaccine is excreted in human milk.

IMOJEV® vaccination is contraindicated in breastfeeding women (see section "Contraindications").

Effect on Ability to Drive

No studies on the effects on the ability to drive or use machines have been performed

UNDESIRABLE EFFECTS

Possible side effects

Like all medicines, **IMOJEV®** can cause side effects, although not everybody gets them.

During clinical trials, the following side effects were reported with the use of **IMOJEV®**:

Adults:

Very common (more than 1 in 10 persons),

• Tiredness (fatigue), feeling unwell (malaise), injection site pain,

• Headache,

• Muscular pain (myalgia).

Common (more than 1 in 100 persons and less than 1 in 10 persons),

• Feeling hot, chills, injection site redness (erythema), injection site itching (pruritus), injection site swelling, injection site bruising,

• Dizziness,

• Joint pain (arthralgia),

• Diarrhoea, nausea, abdominal pain, vomiting,

• Throat pain (pharyngolaryngeal pain), shortness of breath (dyspnea), runny nose (rhinorrhoea), cough,

wheezing, nasal congestion,

• Rash.

Uncommon (more than 1 in 1000 persons and less than 1 in 100 persons),

• Fever (pyrexia)

Rare (more than 1 in 10000 persons and less than 1 in 1000 persons),

• Viral infections such as influenza-like illness

Children:

Very common (more than 1 in 10 persons),

• Fever (pyrexia), feeling unwell (malaise), irritability, injection site pain/tenderness, injection site redness (erythema)

• Headache, sleepiness (somnolence)

• Muscular pain (myalgia)

• Vomiting

• Loss of appetite

• Crying

Common (more than 1 in 100 persons and less than 1 in 10 persons),

• Injection site swelling

Uncommon (more than 1 in 1000 persons and less than 1 in 100 persons),

• Injection site reactions (hardening of skin [induration], bruising, localised swelling filled with blood [haematoma], bleeding [haemorrhage])

• Itchy rash (urticaria)

• Upper respiratory tract infection

Rare (more than 1 in 10000 persons and less than 1 in 1000 persons),

• Injection site itching (pruritus)

• Rash, rash characterized by spot and bump (maculo-papular rash), changes in the colour of the skin after inflammatory reaction (post inflammatory pigmentation change)

• Viral infection

No additional side effect has been identified since the vaccine came on the market.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

OVERDOSE AND TREATMENT

Not documented.

STORAGE CONDITION

Keep out of reach and sight of children.

Store in a refrigerator (2–8°C).

Do not freeze.

Keep the vials in the outer carton in order to protect from light.

Do not use **IMOJEV®** after the expiry date which is stated on the carton after EXP.

DOSAGE FORMS AND PACKAGING AVAILABLE

One dose of powder and one dose of diluent in separate vials (type I glass), each equipped with a stopper (halo-butyl) and a flip off cap (aluminium/polypropylene), with one syringe (polypropylene) and two needles (stainless steel). Pack size of 1 powder vial and 1 diluent vial, 1 syringe and 2 needles.

NAME AND ADDRESS OF MANUFACTURING/ MARKETING AUTHORISATION HOLDER

Manufactured by:

Global Biotech Products Co., Ltd. (For Substipharma Biologics Ltd. as a product owner)

241 Moo 7 Gateway City Industrial Estate, Huasamrong, Plaengyao, Chachoengsao 24190 Thailand

For further product information, please contact Substipharma Biologics Ltd.

DATE OF REVISION OF PACKAGE INSERT

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