

Consumer Medicine Information

What is in this leaflet

Read all of this leaflet carefully before you or your child is vaccinated.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This vaccine has been prescribed for you or your child. Do not pass it on to others.
- 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.

In this leaflet:

- What IMOJEV is and what it is used for
- Before you or your child is given IMOJEV
- How IMOJEV is given
- Possible side effects
- Storing IMOJEV
- Further information

What IMOJEV is and what it is used for

IMOJEV is a vaccine that helps to protect you or your child against Japanese encephalitis.

The vaccine may be administered to persons of 9 months of age and over.

When an injection of IMOJEV is given, the immune system (body's natural defences) will protect against Japanese encephalitis infection. However, as with all vaccines, 100% protection cannot be guaranteed.

In adults, IMOJEV will generally begin protecting against Japanese encephalitis 2 weeks after the injection.

In children, IMOJEV will generally begin protecting against Japanese encephalitis 4 weeks after the injection.

IMOJEV will not prevent Japanese encephalitis if you or your child is incubating the disease before vaccination or if the encephalitis is caused by another virus.

Before you or your child is given IMOJEV

Who should not receive IMOJEV

- If you or your child is allergic (hypersensitive) to the active substance or any of the other ingredients of IMOJEV listed in the Further Information section,
- If you or your child has an illness with febrile or acute disease. The vaccination should be postponed until after you or your child has recovered,
- If you or your child has lowered immunity due to treatment with medicines such as corticosteroids or other medicines used to treat cancer (chemotherapy) (see Taking other medicines section),
- If you or your child has lowered immunity due to diseases including HIV / AIDS or cancer,
- If you are pregnant,

- If you think you may be pregnant, or if you intend to become pregnant within four weeks of vaccination,
- If you are breast-feeding.

Take special care with IMOJEV

Tell your doctor if you or your child has had a blood or plasma transfusion or received injection of immunoglobulins (blood products used to prevent some infections) in the last 3 months. Your doctor may decide to delay vaccination.

Taking other medicines

- If you or your child is taking medicines that may reduce your immune response such as corticosteroids (for example prednisone), medicines used to treat cancer (chemotherapy), radiotherapy or other medicines affecting the immune system, be sure to tell your doctor.

Please tell your doctor or pharmacist if you or your child is taking or has recently taken any other medicines, including medicines obtained without prescription.

Use with other vaccines

Your doctor will advise you if IMOJEV can be given with another vaccine.

In adults, IMOJEV may be given at the same time as the yellow fever vaccine using separate syringes, and injected into separate limbs. In children, IMOJEV may be given at the same time as vaccines against measles, mumps and rubella using separate syringes, and injected into separate limbs from 12 months of age. For children living in or travelling to areas where risk for measles is high, IMOJEV may be given at the same time as vaccines against measles, mumps and rubella from as early as 9 months of age.

Tell your doctor if you or your child has had any vaccine in the last 4 weeks.

Tell your doctor that you or your child has received IMOJEV if another vaccine is to be given within 4 weeks after vaccination.

Pregnancy and breast-feeding

IMOJEV must not be used during pregnancy.

If you are planning to become pregnant, you must wait four weeks after vaccination before trying to conceive.

IMOJEV must not be used during breast-feeding.

How IMOJEV is given

IMOJEV is administered to you or your child by your doctor or your nurse.

Dosage

- Persons from 9 months to 17 years of age: a single dose (0.5 mL) for primary immunisation. If long-term protection is required, a booster dose should be given preferably 1 year after the first vaccination. The booster dose can be given up to 2 years after the first vaccination. Persons aged 18 years and over: a single dose (0.5 mL). There is no need for a booster dose up to 5 years after the first vaccination.

Method and/or route(s) of administration

The doctor or nurse will give IMOJEV as an injection under the skin in the upper arm. For

toddlers (9 to 24 months), IMOJEV can also be given in the upper thigh area.

IMOJEV should not be injected directly into veins.

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

If you have any further questions on the use of this product, ask your doctor or pharmacist.

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 (dyspnoea), 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

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
- Inconsolable 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)
- Upper respiratory tract infection
- Urticaria (itchy rash, hives, welts) Rare (more than 1 in 10000 persons and less than 1 in 1000 persons)
- Injection site itching (pruritus)

- Viral infections
- Rash, rash characterised by spot and bump (maculo-papular rash), changes in the colour of the skin after inflammatory reaction

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.

Storing IMOJEV

IMOJEV is usually stored in the doctor's surgery or clinic, or at the pharmacy.

However, if you need to store IMOJEV:

- Keep out of reach and sight of children.
- Keep IMOJEV in the original pack until it is time for it to be given.
- Keep it in the refrigerator, between 2°C and 8°C. Do not freeze IMOJEV.

Do not use IMOJEV after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not receive IMOJEV if the packaging is torn or shows signs of tampering.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Further Information

What IMOJEV contains

The active substance is Japanese encephalitis virus, live, attenuated: 4.0 - 5.8 log PFU*

* Plaque Forming Unit

The other ingredients are excipients: mannitol, lactose, glutamic acid, potassium hydroxide, histidine, human serum albumin, sodium chloride, water for injections.

No adjuvant or antimicrobial preservative is added.

What IMOJEV looks like and contents of the pack

Each pack of IMOJEV contains

- One vial containing a white to creamy white vaccine powder,
- One vial containing clear diluent,
- One disposable syringe with 2 separate needles.

Your doctor will inject the diluent into the vaccine vial to make the suspension for your injection. After the mixing, IMOJEV is a colourless to amber suspension.

Name and Address of Australian Sponsor

sanofi-aventis australia pty ltd

Talavera Corporate Centre - Building D

12-24 Talavera Road

Macquarie Park

NSW 2113

Telephone: 1800 829 468 (1800 Vaxin8)

AUST R number

AUST R 162215

Date of preparation

8 September 2016

imj-ccds10-cmiv4.1-08sep16