

Imojev®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Imojev?

Imojev contains the active ingredient Japanese encephalitis virus (live, attenuated). Imojev is used to help to protect you or your child against Japanese encephalitis.

For more information, see Section [1. Why am I using Imojev?](#) in the full CMI.

2. What should I know before I use Imojev?

Do not use if you have ever had an allergic reaction to Imojev or any of the ingredients listed at the end of the CMI

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Imojev?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Imojev and affect how it works. Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other vaccines or medicines, including medicines obtained without a prescription.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Imojev?

Imojev is given by your doctor, nurse or pharmacist.

More instructions can be found in Section [4. How do I use Imojev?](#) in the full CMI.

5. What should I know while using Imojev?

Things you should do	
	<p>Tell your doctor, nurse or pharmacist before you receive the vaccine:</p> <ul style="list-style-type: none">• If you or your child is allergic to the active ingredients, or any of the ingredients listed at

the end of this leaflet.
Always check the ingredients to make sure you or your child can use this medicine.

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

	<ul style="list-style-type: none"> • 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.
Looking after your medicine	<ul style="list-style-type: none"> • Imojev is usually stored in the surgery or clinic, or at the pharmacy. However, if you need to store Imojev, keep in the fridge between 2-8°C. Do not freeze.

For more information, see Section [5. What should I know while using Imojev?](#) in the full CMI.

6. Are there any side effects?

Most common side effects in adults include tiredness, feeling unwell, injection site pain, headache, muscular pain, feeling hot, chills, injection site redness, injection site itching, injection site swelling, injection site bruising, dizziness, joint pain, diarrhoea, nausea, abdominal pain, vomiting, throat pain, shortness of breath, runny nose, cough, wheezing, nasal congestion and rash. In children, most common side effects include fever, feeling unwell, irritability, injection site pain, injection site

redness, headache, sleepiness, muscular pain, vomiting, loss of appetite, inconsolable crying and injection site swelling.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Imojev®

Active ingredient(s): Japanese encephalitis virus (live, attenuated)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Imojev. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Imojev.**

Where to find information in this leaflet:

- [1. Why am I using Imojev?](#)
- [2. What should I know before I use Imojev?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Imojev?](#)
- [5. What should I know while using Imojev?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Imojev?

Imojev contains the active ingredient Japanese encephalitis virus (live, attenuated).

Imojev is a vaccine for persons of 9 months of age and over that helps to protect you or your child against Japanese encephalitis.

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.

2. What should I know before I use Imojev?

Warnings

Do not use Imojev:

- If you or your child is allergic to the active ingredients, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you or your child can receive this vaccine.
- 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.

Check with 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.
- takes any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

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.

3. What if I am taking other medicines?

Some medicines may interfere with Imojev and affect how it works.

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.

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Imojev.

4. How do I use Imojev?

How much to use

Imojev is administered to you or your child by your doctor or your nurse as a 0.5 mL injection under the skin in the upper arm. For toddlers (9 to 24 months), Imojev can also be given in the upper thigh area.

- For persons from 9 months to 17 years of age, 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.
- For persons aged 18 years and over there is no need for a booster dose up to 5 years after the first vaccination.
- Imojev should not be injected directly into veins.
- Contact with disinfectants is to be avoided since they may destroy the vaccine.

If you use too much Imojev

If you think that you have used too much Imojev, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Imojev?

Things you should do

Call your doctor straight away if you:

- You notice signs of allergic reaction may include difficulty breathing, shortness of breath, swelling of the face, lips, throat or tongue, cold, clammy skin, palpitations, dizziness, weakness, fainting, rash or itching.

Remind any doctor or dentist you visit that you are using Imojev.

Driving or using machines

Imojev has no or negligible effect on your ability to drive and use machine.

Looking after your medicine

Imojev is usually stored in the doctor's surgery or clinic, or at the pharmacy. However, if you need to store Imojev:

- Keep it where young children cannot reach it.
- Keep Imojev in the original pack until it is time for it to be given.
- Keep it in the refrigerator, store at 2°C to 8°C. Do not freeze Imojev.
- Do not use Imojev after the expiry date which is stated on the carton after EXP.
- Do not use Imojev if the packaging is torn or shows signs of tampering.

Getting rid of any unwanted medicine

Medicines including vaccines 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.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Adults <ul style="list-style-type: none">• Tiredness (fatigue), feeling unwell (malaise), injection site pain• Headache• Muscular pain (myalgia)• 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,	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
<ul style="list-style-type: none"> ● Rash, ● Fever (pyrexia). <p>Children</p> <ul style="list-style-type: none"> ● 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 ● Injection site swelling ● Injection site reactions (hardening of skin [induration], bruising, localised swelling filled with blood [haematoma], bleeding) ● Urticaria (itchy rash, hives, welts) ● Injection site itching (pruritus) 	

Serious side effects

Serious side effects	What to do
<p>Adults</p> <ul style="list-style-type: none">• Viral infections• Throat pain (pharyngolaryngeal pain), shortness of breath (dyspnoea), runny nose (rhinorrhoea), cough, wheezing, nasal congestion. <p>Children</p> <ul style="list-style-type: none">• Upper respiratory tract infection• Viral infections• Rash, rash characterised by spot and bump (maculopapular rash), changes in the colour of the skin after inflammatory reaction	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Imojev contains

Active ingredient (main ingredient)	Japanese encephalitis virus, live, attenuated: 4.0 – 5.8 log PFU* * Plaque Forming Unit
Other ingredients (inactive ingredients)	mannitol, lactose monohydrate, glutamic acid, potassium hydroxide, histidine, human serum albumin, sodium chloride, water for injections.

	No adjuvant or antimicrobial preservative is added.
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Do not take this medicine if you are allergic to any of these ingredients.

What Imojev looks like

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.

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Who distributes Imojev

sanofi-aventis australia pty ltd
12-24 Talavera Road
Macquarie Park NSW 2113
Telephone: 1800 818 806

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