

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 JESPECT?

JESPECT contains the active ingredient *Inactivated Japanese Encephalitis Vaccine (adsorbed)*. JESPECT is used to help prevent you against Japanese Encephalitis.

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

2. What should I know before I use JESPECT?

Do not use if you have ever had an allergic reaction to JESPECT 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 JESPECT?](#) in the full CMI.

3. What if I am taking other medicines?

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

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 JESPECT?

- JESPECT is an injection given by a health professional.

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

5. What should I know while using JESPECT?

| | |
|------------------------------------|--|
| 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 are allergic to the active ingredient or any of the ingredients listed at the end of this leaflet.if you have a high temperature (fever)if you are pregnant or intend to become pregnantif you are breast-feeding or plan to breast-feedif you have an immune system that does not work properly |
| Looking after your medicine | <ul style="list-style-type: none">JESPECT is usually stored in the doctor's surgery or clinic, or at the pharmacy. However, if you need to store JESPECT®, keep it in the refrigerator, between 2°C and 8°C. Do not freeze. |

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

6. Are there any side effects?

The most common side effects include headache, muscle pain, tiredness and nausea. Severe allergic reactions are possible, but rare.

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.

JESPECT[®] (jess-pect)

Active ingredient: *Inactivated Japanese Encephalitis Vaccine (adsorbed)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using JESPECT[®]. **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 JESPECT[®].**

Where to find information in this leaflet:

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

1. Why am I using JESPECT[®]?

JESPECT[®] contains the active ingredient Inactivated Japanese Encephalitis Vaccine (adsorbed).

JESPECT[®] is a vaccine for persons 18 years of age or older used to help prevent Japanese encephalitis (*en-kef-al-i-tis*), a severe and often fatal infection of the brain. Some of those who recover from the disease are often left with brain damage.

Japanese encephalitis is caused by the Japanese encephalitis virus that mainly occurs in Asia. The virus is transmitted to humans by infected mosquitoes that feed on human blood. JESPECT[®] is used to vaccinate persons 18 years and older who:

- Plan to live in or travel to areas where Japanese Encephalitis is common or seasonal. Your doctor will explain your risk of catching the disease.
- Work with Japanese encephalitis virus.

JESPECT[®] works by getting your body to produce its own protection against the Japanese encephalitis virus.

The vaccine does not contain live virus and cannot give you the illness.

After you have been given JESPECT[®], your body makes substances called antibodies. These antibodies fight the Japanese encephalitis virus. When you come into contact with the virus, your body is usually ready to destroy it.

Most people who receive two doses of the vaccine will produce enough antibodies to protect against the disease. However, as with all vaccines, 100% protection cannot be guaranteed.

JESPECT[®] does not protect against encephalitis caused by other viruses or bacteria.

2. What should I know before I use JESPECT[®]?

Warnings

Do not use JESPECT[®] if:

- you are allergic to Japanese Encephalitis vaccine or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- take any medicines for any other condition
- have a high temperature (fever)
- have an immune system that does not work properly
- tend to bleed or bruise easily
- have received or are going to receive other vaccines
- you are under 18 years of age.

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

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor will discuss the possible risks and benefits of having JESPECT[®] during pregnancy and breastfeeding.

3. What if I am taking other medicines?

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.

Some medicines may interfere with JESPECT[®] and affect how it works.

Medicines that may reduce the effect of JESPECT[®] include:

- medicines that suppress your immune system, for example, corticosteroids.

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

4. How do I use JESPECT®?

How much to use

JESPECT® is given to you by a trained health professional as an injection into the upper arm.

- JESPECT® is given as two injections, 28 days apart.
- Each dose of the vaccine is 0.5 mL

When to use JESPECT®

- The vaccination course of JESPECT® should be completed at least one week before potential exposure to the Japanese encephalitis virus.

If you miss the second dose of vaccine, talk to your doctor. It is important that you are given the second dose so that your body can produce enough antibodies to protect against the Japanese encephalitis virus.

Your doctor may decide that you need a booster dose 1–2 years after receiving the vaccine. Your doctor will tell you if a booster dose is required.

If you use too much JESPECT®

As each JESPECT® pre-filled syringe contains only one dose, overdosage is unlikely.

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

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 in Australia or 0800 POISON (0800 764 766) in New Zealand), 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 JESPECT®?

Things you should do

Call your doctor straight away if you:

- Notice sudden signs of allergy such as:
 - rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body
 - shortness of breath, wheezing or trouble breathing
 - collapse

Remind any doctor, dentist or pharmacist you visit that you are using JESPECT®.

Driving or using machines

Do not drive or use machines if you are feeling unwell after vaccination. Wait until any effects of the vaccine have worn off before you drive or use machines.

Looking after your medicine

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

- Keep it in the refrigerator, between 2°C and 8°C. DO NOT FREEZE. Freezing destroys the vaccine.
- Keep it in the original pack until it is time for it to be injected
- Keep it where children cannot reach it.
- Do not use JESPECT® after the expiry date printed on the pack.
- Do not use JESPECT® if the packaging is torn, shows signs of tampering or does not look quite right.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

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 |
|---|--|
| <ul style="list-style-type: none">• reaction at the injection site such as temporary redness, tenderness, itching, pain, bruising, bleeding or swelling• a small lump at the injection site; sometimes this may last for a few weeks• sore throat, runny or blocked nose• muscle pain or stiffness• flu like symptoms, such as headache, fatigue, fever, chills, aching joints• nausea, vomiting, diarrhoea, stomach ache• dizziness• migraine• skin rash• inflammation of the glands. | Speak to your doctor if you have any of these less serious side effects and they worry you. |

Serious side effects

| Serious side effects | What to do |
|--|--|
| <ul style="list-style-type: none"> abnormal sensation like tingling, pricking or numbness painful swelling of the arms or legs. fainting | <p>Call your doctor straight away.</p> |
| <p>Signs of a severe allergic reaction</p> <ul style="list-style-type: none"> rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body shortness of breath, wheezing or trouble breathing collapse. <p>This type of side effect usually occurs within the first few hours of being given the vaccine. These side effects are very rare.</p> | <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 JESPECT® contains

| | |
|---|---|
| Active ingredient (main ingredient) | Inactivated Japanese encephalitis virus strain SA14-14-2 produced in Vero cells: 6 AgU (antigen units). |
| Other ingredients (inactive ingredients) | <ul style="list-style-type: none"> aluminium hydroxide hydrate sodium chloride monobasic potassium phosphate dibasic sodium phosphate |

| | |
|----------------------------|---|
| | <ul style="list-style-type: none"> water for injections. <p>JESPECT® may contain trace amounts of protamine sulfate, formaldehyde and bovine serum albumin</p> |
| Potential allergens | Sulfites: JESPECT may contain trace amounts of sodium metabisulfite. |

Do not take this medicine if you are allergic to any of these ingredients.

What JESPECT® looks like

JESPECT® is supplied as a single dose (0.5 mL) in a needleless pre-filled glass syringe. The vaccine should appear as a clear liquid with a white precipitate and when shaken, it should appear as a white, cloudy suspension.

Registration number

Australia

AUST R 150602

New Zealand

TT50-9020

Who distributes JESPECT®

Sponsor

JESPECT® is distributed in Australia by:

Seqirus Pty Ltd
ABN: 26 160 735 035
63 Poplar Road
Parkville, VIC 3052 Australia

Telephone: 1800 642 865

<http://www.cslseqirus.com.au/>

JESPECT® is distributed in New Zealand by:

Seqirus (NZ) Ltd
PO Box 62 590
Greenlane, Auckland 1546
New Zealand

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