

JESPECT[®] (jess-pect)

Japanese Encephalitis Vaccine (inactivated, adsorbed)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about JESPECT[®].

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines, including vaccines, have risks and benefits. Your doctor has weighed the risks of you having JESPECT[®] against the benefits they expect it will have.

If you have any concerns about this vaccine, talk to your doctor, nurse or pharmacist.

Keep this leaflet. You might need to read it again.

What JESPECT[®] is used for

JESPECT[®] is a vaccine. It helps 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 individual risk of catching the disease
- work with Japanese encephalitis virus.

JESPECT[®] is given as two injections 28 days apart. The vaccination course should be completed at least one week before potential exposure to the Japanese encephalitis virus.

How JESPECT[®] works

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 both 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.

Before you are given JESPECT[®]

When you must NOT be given JESPECT[®]

JESPECT[®] should not be given to any person under 18 years of age.

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.

If you are not sure whether you should have JESPECT[®], talk to your doctor or pharmacist.

Before you are given JESPECT[®]

Tell your doctor if you have allergies to:

- any previous injections of JESPECT[®] or any of the ingredients listed at the end of this leaflet

- any other medicines or vaccines
- any other substances, such as foods, preservatives or dyes.

As for all vaccines, medical supervision and treatment should be available in case there is a severe allergic reaction.

Tell your doctor if you:

- tend to bleed or bruise easily
- are taking any other medicines including medicines you buy without prescription from a pharmacy, supermarket or health food shop
- have a high temperature,
- if your immune system does not work properly
- have had any other travel vaccines.

Tell your doctor if you are pregnant or intend to become pregnant. Your doctor will discuss the possible risks and benefits of having JESPECT® during pregnancy.

How JESPECT® is given

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

How much is given and when

Two doses of vaccine will be given, 28 days apart. Each dose of the vaccine is 0.5 mL.

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.

Ask your doctor or pharmacist to answer any questions you may have.

If you are given too much (overdose)

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

If you think you or anyone else may have been given too much of this medicine

- consult your doctor immediately, or
- telephone the Poisons Information Centre (telephone 13 11 26 in Australia or 0800 POISON (0800 764 766) in New Zealand) for advice, or
- go to Accident and Emergency at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. Urgent medical attention may be required.

After having JESPECT®

Things you must do

Take appropriate precautions to reduce mosquito bites (wear adequate clothing, use

repellents and mosquito nets).

Keep an updated record of your vaccinations.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well after having JESPECT®.

All medicines, including vaccines, can have side effects. JESPECT® may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- 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.

These side effects are usually mild.

Tell your doctor as soon as possible if you notice any of the following:

- abnormal sensation like tingling, pricking or numbness
- painful swelling of the arms or legs.

The above list includes serious side effects that may require medical attention.

Allergic reaction:

As with all vaccines given by injection, there is a very small risk of a severe allergic reaction.

If any of the following happen, tell your doctor or pharmacist immediately, or go to Accident and Emergency at your nearest hospital:

- 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.

These are very serious side effects. If you have them, you may have had a severe allergic reaction to JESPECT[®]. You may need urgent medical attention or hospitalisation. This type of

side effect usually occurs within the first few hours of being given the vaccine. These side effects are very rare.

Other side effects not listed above might occur in some people. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Storing JESPECT[®]

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

- **Keep it where children cannot reach it.**
- Keep it in the original pack until it is time for it to be injected.
- **Keep it in the refrigerator, between 2°C and 8°C. DO NOT FREEZE.** Freezing destroys the vaccine.

Product description

What JESPECT[®] looks like

JESPECT[®] is supplied as a single dose (0.5 mL) in a needle-less 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.

Ingredients in a single dose

Active ingredients:

- Inactivated Japanese encephalitis virus strain SA₁₄₋₁₄₋₂ produced in Vero cells: 6 AgU (antigen units).

Other ingredients:

- aluminium hydroxide
- sodium chloride
- potassium dihydrogen phosphate
- disodium hydrogen phosphate
- water for injections.

JESPECT[®] does NOT contain:

- lactose
- gluten
- tartrazine or
- any other azo dyes
- preservatives.

JESPECT[®] may contain trace amounts of sucrose and protamine sulphate.

Manufacturer/ Distributor

Manufacturer

JESPECT[®] is made by:

Valneva Scotland Ltd.
Oakbank Park Road
EH53 OTG Livingston
United Kingdom

Distributor

JESPECT[®] is distributed in Australia by:

Seqirus (Australia) Pty Ltd
63 Poplar Road
Parkville
Victoria 3052
Australia

**JESPECT® is distributed in
New Zealand by:**

Seqirus (NZ) Ltd
PO Box 62590
Greenlane, Auckland 1546
New Zealand

Registration number

Australia
AUST R 150602

New Zealand
TT50-9020

Date of preparation

August 2017

JESPECT® is a trademark of
Valneva Scotland Ltd