PACKAGE LEAFLET: INFORMATION FOR THE USER

IXIARO suspension for injection
Japanese encephalitis vaccine (inactivated, adsorbed)

Read all of this leaflet carefully before you or your child receive this vaccine because it contains important information for you.
- Keep this leaflet. You and your child may need to read it again.
- If you have any further questions, ask your doctor.
- This vaccine has been prescribed for you and/or your child only. Do not pass it on to others.
- If you and/or your child get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet: See section 4.

What is in this leaflet

1. What IXIARO is and what it is used for

IXIARO is a vaccine against the Japanese encephalitis virus.
The vaccine causes the body to produce its own protection (antibodies) against this disease.

IXIARO is used to prevent infection with the Japanese encephalitis virus (JEV). This virus is mainly found in Asia and is transmitted to humans by mosquitoes that have bitten an infected animal (like pigs). Many infected people develop mild symptoms or no symptoms at all. In people who develop severe disease, JE usually starts as a flu-like illness, with fever, chills, tiredness, headache, nausea, and vomiting. Confusion and agitation also occur in the early stage of disease.

IXIARO should be given only to adults, adolescents, children and infants aged 2 months and older travelling to countries, where JE is endemic or who are at risk through work.

2. What you need to know before you and/or your child receive IXIARO

Do not use IXIARO:
- if you and/or your child are allergic (hypersensitive) to the active substance or any of the other ingredients of this medicine (listed in section 6).
- if you and/or your child have developed an allergic reaction after receiving a former dose of IXIARO. Signs of an allergic reaction may include an itchy rash, shortness of breath and swelling of the face and tongue.
- if you and/or your child are ill with a high fever. In this case, your doctor will postpone the vaccination.

Warnings and precautions
IXIARO must not be injected into a blood vessel.
Primary immunization should be completed at least one week prior to potential exposure to JEV.

Tell your doctor:
- if you and/or your child have experienced any health problems after previous administration of any vaccine.
- if you and/or your child have any other known allergies.

• if you and/or your child have a bleeding disorder (a disease that makes you bleed more than normal) or a reduction in blood platelets, which increases risk of bleeding or bruising (thrombocytopenia).
• if your child is younger than 2 months of age, since IXIARO has not been tested in infants younger than 2 months of age.
• if your or your child's immune system does not work properly (immunodeficiency) or you and/or your child are taking medicines affecting your immune system (such as a medicine called cortisone or cancer medicine).

Your doctor will discuss with you the possible risks and benefits of receiving IXIARO.

Please note that:
• IXIARO cannot cause the disease it protects against.
• IXIARO will not prevent infections caused by other viruses than the Japanese encephalitis virus.
• As with any other vaccine, vaccination with IXIARO may not result in protection in all cases.
• You should take appropriate precautions for you and your child to reduce mosquito bites (adequate clothing, use of repellents, mosquito nets) even after receiving IXIARO.

Other medicines and IXIARO
A study in humans to evaluate the effectiveness and safety of medicines (clinical trial) has shown that IXIARO can be given at the same time with hepatitis A vaccine.

Tell your doctor if you and/or your child are taking or have recently taken, or might take any other medicines, including medicines obtained without a prescription or have recently received any other vaccine.

Pregnancy and breast-feeding
There are limited amount of data from the use of IXIARO in pregnant or breast-feeding women.
As a precautionary measure, the use of IXIARO during pregnancy or breast-feeding should be avoided.
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before receiving this vaccine.

Driving and using machines
IXIARO has no or negligible influence on the ability to drive and use machines.

3. How to use IXIARO

The recommended dosage for adults, adolescents and children aged 3 years of age and older is a total of 2 injections of 0.5 ml each:

• the first injection on Day 0
• the second injection 28 days after the first injection (Day 28).

Babies and children aged 2 months to < 3 years of age
The recommended dosage for babies and children aged 2 months to < 3 years is a total of 2 injections of 0.25 ml each
• the first injection on Day 0
• the second injection 28 days after the first injection (Day 28).

For instruction on the preparation of the 0.25ml dose, please refer to end of this package leaflet.

Make sure you and/or your child finish the complete vaccination course of 2 injections. The second injection should be given at least 1 week before you and/or your child will be at risk of exposure to JE virus. If not, you and/or your child may not be fully protected against the disease.

For adults a booster dose can be given within the second year (i.e. 12 - 24 months) after the first dose of the recommended primary immunization. Your doctor will decide on requirement of booster.

Administration
IXIARO is injected into your or your child's upper arm muscle (deltoid muscle) by your doctor or a nurse. It must not be injected into a blood vessel. In case you and/or your child suffer from a bleeding disorder, your doctor may decide to administer the vaccine under the skin (subcutaneously).
If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you forget to get IXIARO
If you and/or your child miss a scheduled injection, talk to your doctor and arrange another visit for the second injection.
Without the second injection you and/or your child will not be fully protected against the disease. There is data that the second injection can be given up to 11 months after the first one.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The majority of the side effects listed below have been observed during clinical trials. They usually occur within the first 3 days after vaccination, are usually mild and disappear within a few days.

Very common (affects more than 1 user in 10):
headache, muscle pain, injection site pain, tenderness

Common (affects 1 to 10 users in 100):
tiredness, nausea, influenza like illness, fever, injection site reactions (e.g. redness, hardening, swelling, itching)

Uncommon (affects 1 to 10 users in 1,000):
vomiting, skin rash, changes in the lymph-nodes, migraine (throbbing headache, often accompanied by nausea and vomiting and sensitivity to light), dizziness, vertigo (spinning sensation), diarrhoea, belly pain, itching, chills, general, condition of feeling unwell, musculoskeletal stiffness, injection site reactions (bleeding, bruising), abnormal laboratory liver test results (hepatic enzymes increased)

Rare (affects 1 to 10 users in 10,000):
palpitations, rapid heartbeat, difficulty to breathe, abnormal sensation of skin (for example pins and needles), hives, skin redness, pain in leg or arm, joint pain, platelet deficiency, nerve inflammation, limb swelling, and ankle swelling

Additional side effects in children aged 2 months to <3 years

In children aged 2 months to <3 years, the following side effects have been observed more frequently compared to children aged 3 years to <12 years, adolescents and adults:
Very common: fever (28.9%), diarrhoea (11.8%), influenza like illness (11.2%), irritability (11.0%)
Common: loss of appetite, vomiting, skin rash
Uncommon: cough

Reporting of side effects
If you and/or your child get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via via the Medicines and Healthcare products Regulatory Agency (MHRA) at www.mhra.gov.uk/yellowcard.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store IXIARO

- Keep this medicine out of the sight and reach of children.
- Do not use IXIARO after the expiry date which is stated on the carton and label after "EXP". The expiry date refers to the last day of that month.
- Store in a refrigerator (2°C - 8°C).
- Do not freeze. If the vaccine has been frozen it should not be used.
- Store in the original package in order to protect from light.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you and/or your child no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What IXIARO contains

1 dose (0.5 ml) of IXIARO contains:
Japanese encephalitis virus strain SA_{14}-14-2 (inactivated)[1,2] 6 micrograms[3]
corresponding to a potency of ≤ 460 ng ED_{50}

[1] produced in Vero cells
[2] adsorbed on aluminium hydroxide, hydrated (approximately 0.25 milligrams Al^{3+})
[3] total protein content

Aluminium hydroxide is included in this vaccine as an adjuvant.

The other ingredients are: Sodium chloride, potassium dihydrogen phosphate, disodium hydrogen phosphate, water for injections

What IXIARO looks like and contents of the pack

IXIARO is a suspension for injection (0.5 ml in a glass syringe with or without a separate needle, pack size of 1).

IXIARO is a white and slightly milky sterile suspension, which becomes homogenous on shaking.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Valneva Austria GmbH
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Manufacturer:
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This leaflet was last revised in March 2014 .

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu/.

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The following information is intended for medical or healthcare professionals only:

The pre-filled syringe is for single use only and should not be used for more than one person. The pre-filled syringe is ready to use. If a needle is not provided, use a sterile needle.

Do not use if the blister foil is not intact or packaging is damaged.

Upon storage, a fine white deposit with a clear colourless supernatant can be observed.
Before administration, shake the syringe well to obtain a white, opaque, homogeneous suspension. Do not administer if particulate matter remains following shaking or if discoloration is observed or if the syringe appears to be physically damaged.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Information on the administration of a 0.5 ml dose of IXIARO for persons 3 years of age and above

For administration of the full 0.5 ml dose follow the steps below:

1. Shake the syringe to obtain a homogeneous suspension.
2. Remove the syringe tip cap by gently twisting it. Do not attempt to snap or pull the tip off as this may damage the syringe.
3. Attach a needle to the pre-filled syringe.

Information on the preparation of a 0.25 ml dose of IXIARO for use in children below 3 years of age

For administration of a 0.25 ml dose in children aged 2 months to < 3 years, follow the steps below:

1. Shake the syringe to obtain a homogeneous suspension.
2. Remove the syringe tip cap by gently twisting it. Do not attempt to snap or pull the tip off as this may damage the syringe.
3. Attach a needle to the pre-filled syringe.
4. Hold the syringe in an upright position.
5. Push the plunger stopper up to the edge of the red line on the syringe barrel, indicated by a red arrow (see Figure 1)*, to discard excess volume.
6. Attach a new sterile needle prior to injection of the remaining volume.

*If you pushed the plunger stopper beyond the red line, a 0.25 ml dose is not guaranteed and a new syringe should be used.

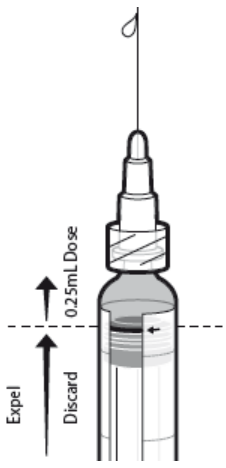

Figure 1: Preparation for Administration of 0.25 ml Dose