

Japanese Encephalitis Vaccine IXIARO® **Patient Information and Consent**

Japanese encephalitis vaccine (inactivated, adsorbed)

IXIARO® is indicated for active immunization against Japanese encephalitis for adults.

IXIARO® should be considered for use in individuals at risk of exposure through travel or in the course of their occupation

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

Japanese Encephalitis is a mosquito-borne viral disease occurring in rural and rice growing areas of Asia and the Far East. Illness ranges from asymptomatic infection to severe encephalitis with a high risk of death or permanent neurological defects (approx 30%) in survivors. It is however estimated that only about 1:200 infections lead to illness.

It is particularly endemic where rice growing and pig farming co-exist, as the mosquito transmits the virus from infected animals, mostly pigs, to humans.

Endemics occur in both rural and urban areas and spread has occurred to previous unaffected areas, leading to severe outbreaks amongst non-immune populations.

Highest transmission rates occur during and just after the wet seasons when mosquitoes are most active, but seasonal patterns vary both within individual countries and from year to year.

Recommendations for immunisation can be made according to whether the country visited has a tropical, subtropical or temperate climate. For the first two, vaccination is recommended before a long stay (one month or longer) in rural areas, especially during the rainy season (monsoon roughly June to September). In temperate climates, outbreaks occur in summer and autumn however local variations such as intensive rice growing or development of pig breeding may interfere with these patterns.

Occasionally immunisation should be considered for shorter trips where there is a high rise of exposure such as, outdoor activities in endemic areas.

Japanese Encephalitis Vaccine IXIARO®

Adults (IXIARO® is not recommended for use in children and adolescents due to lack of data on safety and efficacy)

A seroconversion rate of 29.4 % has been observed 10 days after the first vaccination, and 97.3 % one week after the second vaccination. Hence, **primary immunisation should be completed at least one week prior to potential exposure to Japanese encephalitis virus (JEV).**

The primary vaccination series consists of two doses of 0.5 ml each according to the following schedule:

First dose: at Day 0.

Second dose: 28 days after first dose.

Persistence of protective immunity is unknown. Timing and effect of booster immunisation is currently under investigation.

It is recommended that vaccinees who receive the first dose of IXIARO[®] complete the full vaccination course with IXIARO[®].

Method of administration

The vaccine should be administered by intramuscular injection into the deltoid muscle. It should never be injected intravascularly.

Exceptionally, IXIARO[®] can also be administered subcutaneously to patients with thrombocytopenia or bleeding disorders since bleeding may occur following an intramuscular administration. Subcutaneous administration could lead to a suboptimal response to the vaccine (see section 4.4). However, it should be noted that there are no clinical efficacy data to support administration by the subcutaneous route.

Contra indications

- Hypersensitivity to the active substance or to any of the excipients or to any residuals (e.g. protamine sulphate).
- Individuals who show hypersensitivity reactions after receiving the first dose of the vaccine should not be given the second dose.
- Administration must be postponed in persons with acute severe febrile conditions.
- Pregnancy
- History of heart, liver or kidney disease
- Leukaemia or Lymphoma
- Any generalised malignancy

Possible Adverse Reactions

Approximately 40% of treated subjects can be expected to experience adverse reactions. They usually occur within the first three days after vaccination, are usually mild and disappear within a few days. No increase in the number of adverse reactions was noted between first and second doses.

Most common side effect is headache and myalgia

Rarely-redness and soreness at injection site

Japanese Encephalitis Vaccine Consent

Name..... DOB.....

Address.....

I have read and understand the information about Japanese Encephalitis vaccine. It is only administrable to me as I am travelling to an "at risk" area, however I understand that it is important that I continue with adequate mosquito bite prevention.

I consent to the Japanese Encephalitis vaccine course which is charged privately.

Signature.....

Date.....

Patient/Parent/Guardian

Are you the Father on the birth certificate and have parental consent? **Yes/No***

Are you the Mother on the birth certificate and have parental consent? **Yes/No***

IF NOT this episode of care needs to be postponed and you will need to bring a letter to the surgery for each contact of care **from the person with parental consent.**

*please delete as appropriate

Parental Signature.....

Child under 16yrs

Date.....

Review 08.11
Next review due 2013