IXIARO®

Prescribing Information: IXIARO® suspension for injection in prefilled syringe Japanese encephalitis vaccine (inactivated, adsorbed). **Presentation:** Each 0.5ml pre-filled syringe of IXIARO® contains: 6 AU (antigen units) of inactivated Japanese encephalitis virus (SA14-14-2 strain, produced in Vero cells), corresponding to a potency of ≤460ng ED50, adsorbed on approximately 0.25mg aluminium hydroxide. **Indications:** IXIARO® is indicated for active immunisation against Japanese encephalitis in adults, adolescents, children and infants aged 2 months and older. **Dosage:** *Primary dose: Infants 2 months of age to <3 years of age:* Two doses of 0.25ml each, first dose at day 0, second dose day 28. *Children 3 years of age to <18 years of age:* Two doses of 0.5ml each, first dose at day 0, second dose day 28. *Adults:* The primary vaccination series consists of two separate doses of 0.5ml each, according to the following conventional schedule: First dose at Day 0. Second dose: 28 days after first dose. ***Rapid schedule:*** Persons aged 18-65 years can be vaccinated in a rapid schedule as follows: First dose at Day 0. Second dose: 7 days after first dose. Vaccinees who receive the first dose of IXIARO® should complete the full vaccination course. *Booster Dose:* A third does should be given within the second year (12-24 months) after the primary vaccination course, prior to potential re-exposure to JEV. Long-term seroprotection data following a first booster dose administered 12–24 months after primary immunisation suggest that a second booster should be given 10 years after the first booster dose, prior to potential exposure to JEV. *Elderly (>65 years of age):* The primary vaccination series consists of two separate doses of 0.5ml each, according to the following conventional schedule: First dose at Day 0. Second dose: 28 days after first dose. If the primary immunisation of two injections is not completed, full protection against the disease might not be achieved. *Booster dose:* As with many vaccines, the immune response in elderly persons (>65 years of age) to IXIARO® is lower than in younger adults. Duration of protection is uncertain in elderly persons (>65 years of age), therefore a booster dose (third dose) should be considered before any further exposure to JE virus. Long-term seroprotection in this group following a booster-dose is not known. Booster dose *(Children and adolescents)*: A booster dose (third dose) should be given within the second year (i.e.12–24 months) after primary immunisation, prior to potential re-exposure to JEV. Children and adolescents at continuous risk for acquiring Japanese encephalitis (residing in endemic areas) should receive a booster dose at month 12 after primary immunisation. **Administration:** Intramuscular injection into the deltoid muscle. In infants, the anterolateral aspect of the thigh may be used as injection site. It should never be injected intravascularly. IXIARO® can also be administered subcutaneously in patients with thrombocytopenia or bleeding disorders. When IXIARO® is administered concomitantly with injectable vaccines, they should be given with separate syringes at opposite sites. **Contraindications:** Hypersensitivity to the active substance, excipients or residuals. Individuals who show hypersensitivity reactions after the first dose of IXIARO® should not be given the second dose. Administration must be postponed in persons with acute, severe febrile conditions. **Warnings and Precautions:** Appropriate medical treatment and supervision should be readily available in case of a rare anaphylactic event following the administration of the vaccine. IXIARO® will not protect against encephalitis caused by other micro-organisms. IXIARO® should not be administered intramuscularly to persons with thrombocytopenia, haemophilia or other bleeding disorders. Primary immunisation should be completed at least one week prior to potential exposure to Japanese encephalitis virus. IXIARO® may not result in protection in all cases. **Interactions:** No interaction studies have been performed in children and adolescents. Concomitant administration of IXIARO® with inactivated hepatitis A vaccine and with inactivated rabies vaccine in two different schedules has been evaluated in clinical studies. There was no interference with the immune response to Japanese encephalitis virus (JEV) or to hepatitis A or rabies virus vaccines. The safety profiles of IXIARO® and the other studied vaccines were not compromised when administered concomitantly. People receiving immunosuppressive therapy or patients with immunodeficiency may not develop an adequate response to IXIARO®. **Fertility, Pregnancy and Lactation:** Use of IXIARO®

should be avoided during pregnancy or lactation due to limited data. It is unknown whether IXIARO® is excreted in human milk. No effects on breastfed newborns/infants are anticipated since the systemic exposure of breast-feeding women to IXIARO® is negligible. A study in rats did not indicate vaccine-related effects on female reproduction, foetal weight, survival and development of the off-spring. **Effect on ability to drive and use machines:** IXIARO® has none or negligible influence. **Side effects: Adult and older adults (>65 years):** Very common/common: headache, myalgia, injection site reactions, (pain, tenderness, redness, hardening, swelling, itching), nausea, fatigue, influenza-like illness, pyrexia. Uncommon: asthenia, lymphadenopathy, migraine, dizziness, vertigo, vomiting, diarrhoea, abdominal pain, rash, pruritus, musculoskeletal stiffness, chills, malaise, increased hepatic enzymes, hyperhidrosis, arthralgia. Rare: syncope, thrombocytopenia, paraesthesia, neuritis, palpitations, tachycardia, dyspnoea, urticaria, erythema, pain in extremity, peripheral oedema, dysgeusia, eyelid oedema. For frequencies of these side effects in infants and children <18 years of age, please refer to Summary of Product Characteristics. **Overdose:** No symptoms related to overdose were reported in the paediatric population. Inadvertent administration of an 0.5ml dose of IXIARO® in children aged 1 to <3 years does not pose any safety concerns. **Legal category:** POM. **Packaging Quantities:** Pack of 1 pre-filled syringe. Basic cost: £62.48 per dose. **Marketing authorisation holder:** Valneva Austria GmbH. Campus Vienna Biocenter 3, A-1030 Vienna, Austria. **Marketing authorisation numbers:** PLGB 43185/0001.

For full prescribing information and details of other side effects please refer to the Summary of Product Characteristics which can be found at www.medicines.org.uk/emc

Full prescribing information is available on request from: Medical Information, VALNEVA AUSTRIA GMBH, Campus Vienna Biocenter 3, 1030 Vienna, Vienna, Austria, FB-Nr: FN 389960 x / HG Wien. Telephone: +44 1506 446608. Email: medinfo@valneva.com

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Adverse events should be reported.
Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
Adverse events should also be reported to the Valneva UK Ltd Medical Information department on Tel: 01506 446608 or via email: safety@valneva.com