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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
IXIARO

Common Name: **Japanese Encephalitis vaccine, inactivated, adsorbed**

On 18 December 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product IXIARO, containing a target total protein amount of 6µg per 0.5 ml adsorbed to aluminium hydroxide, suspension for injection, intended for active immunisation against Japanese encephalitis for persons aged 18 years and older. IXIARO was designated as an orphan medicinal product on 24 January 2006. The applicant for this medicinal product is Intercell AG.

The active substance of IXIARO is Japanese encephalitis virus (attenuated strain SA₁₄-14-2 (inactivated) produced in Vero cells), an Encephalitis Virus vaccines (J07BA02). The vaccine induces the generation of neutralizing antibodies that have been implicated in conferring protection against Japanese encephalitis.

The benefits with IXIARO are its protection against Japanese encephalitis. The most common side effects are headache and myalgia usually occurring in the first three days after vaccination.

A pharmacovigilance plan for IXIARO, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: "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."

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for IXIARO and therefore recommends the granting of the marketing authorisation.

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Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

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Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.