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Please note that this product was withdrawn from the Community Register of designated Orphan Medicinal Products in March 2009 on request of the Sponsor

Committee for Orphan Medicinal Products

Public summary of positive opinion for orphan designation of purified inactivated Japanese encephalitis SA14-4-2 virus vaccine for the prevention of Japanese encephalitis

On 24 January 2006, orphan designation (EU/3/05/348) was granted by the European Commission to Intercell AG, Austria, for purified inactivated Japanese encephalitis SA14-4-2 virus vaccine for the prevention of Japanese encephalitis.

What is Japanese encephalitis?

Japanese encephalitis is a disease caused by the Japanese encephalitis SA14-4-2 virus, which causes an inflammation of the membranes around the brain (encephalitis) in humans. Certain types of mosquitoes carry the virus from animals (mostly pigs) to humans. Japanese encephalitis virus cannot be transmitted from person-to-person even through mosquito bites. Japanese encephalitis is a leading cause of viral encephalitis in Asia. It occurs from the islands of the Western Pacific in the east to the Pakistani border in the west, and from Korea in the north to Papua New Guinea in the south. Japanese encephalitis distribution is known to be linked to irrigated rice production combined with pig rearing. Most Japanese encephalitis virus infections are mild (fever and headache) or without apparent symptoms, but approximately 1 in 200 infections results in severe disease and sometimes death. The disease is characterized by rapid onset of high fever, headache and other more serious effects due to the inflammation of the membranes around the brain, that in some patients could lead to long-term or permanent disability even after recovery.

Japanese encephalitis might occur among travellers to Eastern and South Eastern Asia and can be chronically debilitating and life-threatening.

What is the estimated number of patients at risk of developing the condition*?

At the time of designation, the number of patients at risk of Japanese encephalitis was estimated to be less than 3 people in 10,000 in the European Union (EU) *. This is equivalent to a total of fewer than 138,000 people, which is below the threshold for orphan designation, which is 5 people in 10,000. This is based on the information provided by the sponsor and knowledge of the Committee for Orphan Medicinal Products (COMP).

What methods of prevention are available?

Preventive measures against infection are the standard anti-mosquito precautions. There are at present no products authorised in the EU for prevention of the condition but there is a vaccine used for Japanese encephalitis, which can be made available upon request.

*Disclaimer: For the purpose of the designation, the number of patients affected by the condition is estimated and assessed on the basis of data from the European Union (EU 25), Norway, Iceland and Liechtenstein. This represents a population of 459,700,000 (Eurostat 2004).

How is this medicine expected to work?

Purified inactivated Japanese encephalitis SA-14-4-2 virus vaccine is a vaccine made of a specific killed Japanese encephalitis virus, called SA-14-4-2. Once injected in the body, it can stimulate the body's defense system (immune system), aimed at building an immune response as a protection against a potential infection of the similar (active) virus.

What is the stage of development of this medicine?

At the time of submission of the application for orphan designation, clinical trials in subjects at risk of Japanese encephalitis were ongoing.

Purified inactivated Japanese encephalitis SA-14-4-2 virus vaccine was not authorised anywhere worldwide for the prevention of Japanese encephalitis or designated as orphan medicinal product elsewhere for this condition, at the time of submission.

According to Regulation (EC) No 141/2000 of 16 December 1999, the Committee for Orphan Medicinal Products (COMP) adopted on 7 December 2005 a positive opinion recommending the grant of the above-mentioned designation.

Opinions on orphan medicinal product designations are based on the following three criteria:

- the seriousness of the condition;
- the existence of alternative methods of diagnosis, prevention or treatment;
- either the rarity of the condition (affecting not more than 5 in 10,000 people in the Community) or insufficient returns on investment.

Designated orphan medicinal products are products that are still under investigation and are considered for orphan designation on the basis of potential activity. An orphan designation is not a marketing authorisation. As a consequence, demonstration of quality, safety and efficacy is necessary before a product can be granted a marketing authorisation.

For more information:

Sponsor's contact details:

Intercell AG

Campus Vienna Biocenter 3

A-1030 Vienna

Austria

Telephone: +43 1 20 62 03 03

Telefax: +43 1 20 62 08 10

E-mail: orphandrug@intercell.com

Patients' association contact point: Not available

**Translations of the active ingredient and indication in all EU languages
and Norwegian and Icelandic**

Language	Active Ingredient	Indication
English	Purified inactivated Japanese encephalitis SA14-4-2 virus vaccine	Prevention of Japanese encephalitis
Czech	Purifikovaný inaktivovaná vakcína viru SA 14-4-2 Japonské encefalitidy	Prevence japonské encefalitidy
Danish	Renset, inaktiveret Japansk encephalitis SA14-4-2 virus vaccine	Forebyggelse af japansk encephalitis
Dutch	Gezuiverd geïnactiveerd Japanse encefalitis SA14-4-2 virus vaccin	Preventie van Japanse encefalitis
Estonian	Puhastatud inaktiveeritud Jaapani entsefaliidi Sa14-4-2 viiruse vaktsiin	Jaapani entsefaliidi preventsoon
Finnish	Puhdistettu, inaktivoitu Japanilainen aivotulehdusvirusrokote (SA 14-4-2)	Japanilaisen aivotulehduksen esto
French	Vaccin inactivé et purifié contre le virus de l'encéphalite japonaise	Prévention de l'encéphalite japonaise
German	Gereinigt inaktivierter Japanische Virusencephalitis Impfstoff SA14-4-2	Prävention der Japanischen Virusencephalitis
Greek	Εμβόλιο που περιέχει καθαρό αδρανοποιημένο ιό SA14-4-2 ιαπωνικής εγκεφαλίτιδας virus vaccine	Πρόληψη της ιαπωνικής εγκεφαλίτιδας
Hungarian	Tisztított, inaktívált japán encephalitis SA14-4-2 vírus vakcina	Japán encephalitis prevenciója
Italian	Vaccino derivato dal virus dell'encefalite giapponese SA14-4-2 purificato e inattivato	Prevenzione dell'encefalite giapponese
Latvian	Attīrīta inaktīvēta Japānas encefalīta SA 14-4-2 vīrusa vakcīna	Japānas encefalīta profilaksei
Lithuanian	Išgryninta inkatyvuota japoniškojo encefalito SA 14-4-2 viruso vakcina	Japoniškojo encefalito prevencija
Polish	Szczepionka przeciw japońskiemu zapaleniu mózgu, inaktywowana, oczyszczona, szczep SA 14-4-2	Zapobieganie japońskiemu zapaleniu mózgu
Portuguese	Vacina do vírus da encefalite japonesa SA 14-4-2 purificado e inativado	Prevenção da encefalite japonesa
Slovak	Vakcína obsahujúca purifikovaný inaktivovaný vírus japonskej encefalitídy SA14-4-2	Prevenca japonskej encefalitídy
Slovenian	Prečiščena vakcina zinaktiviranim virusom SA 14-4-2 japonskega encefalitisa (Preprečevanje japonskega encefalitisa
Spanish	Vacuna del virus de la encefalitis japonesa SA 14-4-2, inactivado y purificado	Prevenición de la encefalitis japonesa
Swedish	Renat inaktiverat japansk encefalit SA14-4-2 virusvaccin	Profylax av japansk encefalit
Norwegian	Renset, inaktivert japansk encefalitt SA14-4-2 virus vaksine	Profylakse mot japansk encefalitt
Icelandic	Japönsk heilabólguveira SA14-4-2, hreinsuð og deydd	Til að fyrirbyggja japanska heilabólgu