



The European Agency for the Evaluation of Medicinal Products
Human Medicines Evaluation Unit

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**PUBLIC STATEMENT ON
HEPACARE (Triple antigen hepatitis B recombinant vaccine)**

WITHDRAWAL OF THE MARKETING AUTHORISATION IN THE EUROPEAN UNION

On 4 August 2000 the European Commission granted a marketing authorisation for the whole European Union to Medeva Pharma Limited, now known as Celltech Pharmaceuticals Ltd, for HEPACARE (Triple antigen hepatitis B recombinant vaccine), indicated for active immunisation against hepatitis B virus infection in non-immune adults (≥ 18 years).

HEPACARE was not marketed anywhere in the world. On 23 August 2002 the Marketing Authorisation Holder notified the European Commission of its decision to voluntarily withdraw the Marketing Authorisation for HEPACARE for commercial reasons. Alternatives are available in Europe, either as mono-component or combined vaccines.

On 23 October 2002 the European Commission adopted the decision withdrawing the Marketing Authorisation for the medicinal product for human use "HEPACARE". Pursuant to this decision the European Public Assessment Report for HEPACARE has been removed from the EMEA website.

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