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Evaluation of Medicines for Human Use
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Public Statement

ImmunoGam

Human Hepatitis B Immunoglobulin

On 15 March 2010 the European Commission granted a marketing authorisation for the whole European Union to Cangene Europe Limited for ImmunoGam (Human Hepatitis B Immunoglobulin).

ImmunoGam (Human Hepatitis B Immunoglobulin) is a solution for injection that contains the active substance human hepatitis B immunoglobulin.

ImmunoGam was indicated for the prevention of hepatitis B virus recurrence after liver transplantation in HBsAg-positive patients and immunoprophylaxis of hepatitis B.

On 17 August 2010, the marketing authorisation holder (MAH) responsible for ImmunoGam has requested the voluntary withdrawal of ImmuoGam from the Community Register.

The European Commission adopted the decision to withdraw, at the holder's request, the marketing authorisation granted by Decision C(2010)1810 for ImmunoGam (Human Hepatitis B Immunoglobulin) on 6 September 2010.

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