19 November 2015
EMA/CHMP/729343/2015
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (post authorisation)**

# Zutectra

## human hepatitis B immunoglobulin

On 19 November 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Zutectra. The marketing authorisation holder for this medicinal product is Biotest Pharma GmbH.

The CHMP adopted a change to the existing indication as follows[2]:

"Prevention of hepatitis B virus (HBV) re-infection in **HBsAg and** HBV-DNA negative adult patients at least **one week** ~~6 months~~ after liver transplantation for hepatitis B induced liver failure. **HBV-DNA negative status should be confirmed within the last 3 months prior to OLT. Patients should be HBsAg negative before treatment start.**

The concomitant use of adequate virostatic agents should be considered~~, if appropriate,~~ as standard of hepatitis B re-infection prophylaxis."

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] New text in bold, removed text as strikethrough

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