European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

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

Common name: ***human hepatitis B immunoglobulin***

On 24 September 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Zutectra, 500 IU, Solution for injection, intended for the prevention of hepatitis B virus (HBV) re-infection in HBV-DNA negative patients more than 6 months after liver transplantation for hepatitis B induced liver failure. The applicant for this medicinal product is Biotest Pharma GmbH.

The active substance of Zutectra is human hepatitis B immunoglobulin, a specific immunoglobulin medicinal product (J06BB04). The mechanism of action of hepatitis B immunoglobulin is a passive immunisation against infection with the hepatitis B virus.

The benefits with Zutectra are its ability to maintain anti-HBs serum levels in line with those required for hepatitis B immunoglobulin preparations (> 100 IU/l). This was demonstrated in a study monitoring trough levels of anti-HBs in 23 stable HBsAg-negative, HBV DNA-negative liver transplant patients. In addition, the pharmacokinetic profile was characterised. The product is for subcutaneous use and allows for self-administration which is considered a convenient and feasible alternative provided appropriate training is given, initial supervision is in place and monitoring of anti HBsAg levels is carried out regularly. The most common side effects are injection site reactions (pain, urticaria, haematoma) as well as unspecific hypersensitivity reactions such as headache and upper abdominal pain.

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

The approved indication is: “Prevention of hepatitis B virus (HBV) re-infection in HBV-DNA negative patients more than 6 months after liver transplantation for hepatitis B induced liver failure. Zutectra is indicated in adults only. 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 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 Zutectra 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.

** 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.

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