24 February 2022
EMA/CHMP/87383/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

PreHevbri

Hepatitis B vaccine (recombinant, adsorbed)

On 24 February 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product PreHevbri, intended for the active immunisation against hepatitis B virus infection (HBV).

The applicant for this medicinal product is VBI Vaccines B.V.

PreHevbri will be available as a 10 µg suspension for injection. The active substances of PreHevbri, a hepatitis B vaccine, are hepatitis B surface antigens (HBsAg) S [83%], pre-S1 [11%] and pre-S2 [6%] (ATC code: J07BC01). PreHevbri induces the production of specific humoral antibodies against HBsAg. Antibody concentrations of at least 10 mIU/mL against HBsAg are known to confer protection against hepatitis B virus infection.

The benefits with PreHevbri are its ability to induce protective levels of antibody after the third dose of the vaccine. PreHevbri contains an adjuvant, a substance which improves the body's production of antibodies and makes the protection last longer.

The most common side effects are feeling very tired, pain or tenderness at the injection site, itching at the injection site, muscle pain and headache.

The full indication is:

> PreHevbri is indicated for active immunisation against infection caused by all known subtypes of the hepatitis B virus in adults.
>
> It can be expected that hepatitis D will also be prevented by immunisation with PreHevbri as hepatitis D (caused by the delta agent) does not occur in the absence of hepatitis B infection.
>
> The use of PreHevbri should be in accordance with official recommendations.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and

[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

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made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.