10 December 2020
EMA/CHMP/601178/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Heplisav B

hepatitis B surface antigen

On 10 December 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Heplisav B, intended for the active immunisation against hepatitis B virus infection (HBV). The applicant for this medicinal product is Dynavax GmbH.

Heplisav B will be available as solution for injection in pre-filled syringe. The active substance in Heplisav B, a hepatitis vaccine, is a hepatitis B surface antigen (HBsAg) (ATC code: J07BC01). Heplisav B induces specific humoral antibodies against HBsAg. Antibody concentrations of at least 10 mIU/mL against HBsAg are recognised to confer protection against hepatitis B virus infection.

The benefits with Heplisav B are its ability to induce protective levels of antibody after the second dose of the vaccine. Heplisav B 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 headache, muscle aches, feeling tired, pain at the spot where the injection was given, feeling unwell (malaise).

The full indication is:

> Heplisav B is indicated for the active immunisation against hepatitis B virus infection (HBV) caused by all known subtypes of hepatitis B virus in adults 18 years of age and older.
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> The use of Heplisav B should be in accordance with official recommendations.
>
> It can be expected that hepatitis D will also be prevented by immunisation with Heplisav B as hepatitis D (caused by the delta agent) does not occur in the absence of hepatitis B infection.

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 made available in all official European Union languages after 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

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