



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Heplisav B (*hepatitis B vaccine (recombinant, adjuvanted)*)

An overview of Heplisav B and why it is authorised in the EU

What is Heplisav B and what is it used for?

Heplisav B is a vaccine for preventing hepatitis B virus infection in adults. It is also likely to prevent infection with the hepatitis D virus as this virus is only present in people with hepatitis B infection.

Heplisav B is used in accordance with official recommendations. It contains a protein from the hepatitis B virus.

How is Heplisav B used?

Heplisav B is given as two injections into the muscle of the upper arm 1 month apart.

For more information about using Heplisav B, see the package leaflet or contact your doctor or pharmacist.

How does Heplisav B work?

Heplisav B is a vaccine. Vaccines work by preparing the immune system (the body's natural defences) to defend the body against a specific disease.

Heplisav B contains a protein found on the hepatitis B virus. When a person is given the vaccine, the immune system recognises the protein in the vaccine as foreign and makes antibodies against it. If the person then comes into contact with virus, these antibodies, together with other components of the immune system, will be able to fight off the virus more effectively and so help protect the person against the infection. The vaccine also contains an adjuvant to stimulate a better response.

What benefits of Heplisav B have been shown in studies?

Results from three main studies involving over 13,000 participants showed that Heplisav B was more effective than Engerix B (another hepatitis B vaccine) at stimulating an immune response against the virus. Taken together the studies found that around 96% of people given Heplisav B developed enough antibodies to kill off the virus and protect against the disease compared with 80% of those given Engerix B.

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People given Heplisav B also had higher levels of antibodies and sufficient levels developed earlier with Heplisav B than with Engerix B.

What are the risks associated with Heplisav B?

The most common side effects with Heplisav B (which may affect more than 1 in 10 people) are pain at the injection site, headache, feeling generally unwell, tiredness, muscle pain and fever.

People who have a severe allergic reaction after the first dose should not have a second dose. The vaccine should also not be given to people allergic to yeast.

For the full list of restrictions and side effects, see the package leaflet.

Why is Heplisav B authorised in the EU?

Studies have shown that Heplisav B provides protection against hepatitis B infection in 96% of people given the vaccine. Side effects occurred slightly less frequently with this vaccine than with the comparator vaccine (Engerix B) and they are considered manageable.

The European Medicines Agency therefore concluded that Heplisav B's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Heplisav B?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Heplisav B have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Heplisav B are continuously monitored. Side effects reported with Heplisav B are carefully evaluated and any necessary action taken to protect patients.

Other information about Heplisav B

Heplisav B received a marketing authorisation valid throughout the EU on 18 February 2021.

Further information on Heplisav B can be found on the Agency's website:
ema.europa.eu/medicines/human/EPAR/heplisav-b

This overview was last updated in 02-2021.