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PreHevbri (Hepatitis B vaccine [recombinant, adsorbed])

An overview of PreHevbri and why it is authorised in the EU

What is PreHevbri and what is it used for?

PreHevbri is a vaccine for adults that is used in line with official recommendations to protect against hepatitis B (an infectious disease of the liver caused by hepatitis B virus). By preventing hepatitis B, the vaccine is also expected to protect against hepatitis D (another disease of the liver, caused by the hepatitis D virus).

PreHevbri contains three proteins from the outer part of the hepatitis B virus.

How is PreHevbri used?

PreHevbri is available as a suspension for injection. It can only be obtained with a prescription. The vaccination schedule consists of three doses, to be given in the muscle of the upper arm. The second and third vaccinations should be given one month and six months after the first dose.

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

How does PreHevbri work?

PreHevbri is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) to defend itself against a disease. PreHevbri contains three different proteins that are found on the outside 'envelope' of the hepatitis B virus. These proteins (known as surface antigens) are adsorbed (fixed) to an aluminium compound to help stimulate the immune response. When a person is given the vaccine, the immune system recognizes the different parts of the surface antigen as 'foreign' and makes antibodies against them. When a person later comes into contact with hepatitis B virus, the immune system will be able to produce antibodies more quickly, and this helps to protect against hepatitis B. PreHevbri does not contain the virus itself and cannot cause hepatitis B.

The virus that causes hepatitis D is a so-called incomplete virus. It cannot make copies of itself without the help of hepatitis B virus. Therefore, by protecting against hepatitis B, PreHevbri is also expected to protect against hepatitis D.

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What benefits of PreHevbri have been shown in studies?

The benefits of PreHevbri were evaluated in two main studies in 4,445 adults which compared the immune response to the vaccine with that to Engerix B (another hepatitis B vaccine). The main measure of effectiveness was the percentage of people who had protective levels of antibodies four weeks after they had received their third vaccination. The results from both studies showed that PreHevbri was at least as effective as the other hepatitis B vaccine.

In the first study, involving adults from 18 to over 70 years of age, 91.4% (656 out of 718) people who were given three doses of PreHevbri and 76.5% (553 out of 723) people who were given three doses of the other hepatitis B vaccine produced protective levels of antibodies. In people from 45 years of age, 89.4% of those given PreHevbri (559 out of 625) produced protective levels of antibodies compared with 73.0% of those given the other vaccine (458 out of 627). In the second study in adults aged 18 to 45 years, 1,740 out of 1,753 (99.3%) people given PreHevbri and 561 out of 592 (94.8%) people given the other vaccine were protected after they completed their vaccination course.

What are the risks associated with PreHevbri?

The most common side effects with PreHevbri (which may affect more than 1 in 10 people) are reactions such as tenderness and itching at the site of injection, muscle pain, tiredness, and headache. For the full list of side effects of PreHevbri, see the package leaflet.

PreHevbri must not be used in people who are hypersensitive (allergic) to the active substance or any of the other ingredients of the vaccine, or in those who have had a severe allergic reaction after being given any other hepatitis B vaccine.

Why is PreHevbri authorised in the EU?

PreHevbri was shown to be at least as effective as another hepatitis B vaccine. Protective levels of antibodies were seen in older participants and those with chronic conditions such as diabetes (who might be expected to have a weaker immune response), as well as in younger, fitter individuals. Though local reactions seemed to be somewhat more common with PreHevbri than with the comparator vaccine, they were largely mild to moderate, and the safety profile was considered acceptable. The European Medicines Agency therefore decided that the benefits of PreHevbri 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 PreHevbri?

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

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

Other information about PreHevbri

PreHevbri received a marketing authorisation valid throughout the EU on 25 April 2022.

Further information on PreHevbri can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/PreHevbri

This overview was last updated in May-2022.