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EPAR summary for the public

HBVaxPro

hepatitis B vaccine (rDNA)

This is a summary of the European public assessment report (EPAR) for HBVaxPro. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for HBVaxPro.

What is HBVaxPro?

HBVaxPro is a vaccine, which is available as a suspension for injection in vials and pre-filled syringes. It contains parts of the hepatitis B virus as the active substance. HBVaxPro is available in two strengths (10 and 40 micrograms/ml).

What is HBVaxPro used for?

HBVaxPro is used to vaccinate against hepatitis B in people who are at risk of exposure to the hepatitis B virus, as determined on the basis of official recommendations.

The medicine can only be obtained with a prescription.

How is HBVaxPro used?

A course of vaccination should include at least three injections of HBVaxPro. The recommended dose for children from birth up to the age of 15 years is 0.5 ml of the lower strength (10 micrograms/ml) at each injection. For adults and adolescents aged 16 years of age and older, 1 ml of the lower strength is given at each injection. The higher strength (40 micrograms/ml) is used in patients who are undergoing or are about to undergo dialysis (a blood clearance technique).

HBVaxPro is usually given as an injection into the muscle of the thigh in babies and infants, and of the shoulder in children, adolescents and adults.

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The timing of injections depends on the patient's age, strength of the immune system, response to vaccination and likelihood of exposure to the hepatitis B virus. For full details, see the summary of product characteristics (also part of the EPAR).

How does HBVaxPro work?

HBVaxPro is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. HBVaxPro contains small amounts of 'surface antigens' (proteins from the surface) of the hepatitis B virus. When a person is given the vaccine, the immune system recognises the surface antigens as 'foreign' and makes antibodies against them. The immune system will then be able to produce antibodies more quickly when the person is naturally exposed to the viruses. This helps to protect against infection with the hepatitis B virus.

The surface antigens in HBVaxPro are produced by a method known as 'recombinant DNA technology': they are made by a yeast that has received a gene (DNA), which makes it able to produce the proteins. The surface antigens are also 'adsorbed'. This means that they are fixed onto aluminium compounds to help stimulate a better response.

HBVaxPro was specifically developed from a vaccine that was already in use in the European Union (EU), in order to produce a vaccine that does not contain the preservative thiomersal.

How has HBVaxPro been studied?

Because the active substance used in HBVaxPro was already authorised for use in the EU, there have been no formal studies with HBVaxPro. The company provided information comparing other vaccines with and without thiomersal, including studies of a vaccine that contains the same active substance as HBVaxPro.

What benefit has HBVaxPro shown during the studies?

The results of the studies presented showed that the thiomersal-free vaccines produced protective levels of antibodies against hepatitis B virus to a similar extent to the vaccines that contained thiomersal at the end of the vaccination course. This included the vaccines that contain the same active substance as HBVaxPro.

What is the risk associated with HBVaxPro?

The most common side effects with HBVaxPro (seen in between 1 and 10 patients in 100) are reactions at the injection site, including temporary soreness, erythema (redness) and induration (hardening). For the full list of all side effects reported with HBVaxPro, see the package leaflet.

HBVaxPro should not be given to people who may be hypersensitive (allergic) to the active substance or any of the other ingredients including substances present at very low (trace) levels, such as formaldehyde and potassium thiocyanate, used in the manufacture of the vaccine. Vaccination should be postponed for people with a severe illness with fever.

Why has HBVaxPro been approved?

The CHMP concluded that the removal of thiomersal from vaccines did not reduce their effectiveness in protecting against hepatitis B virus infection, but reduced their risks. Therefore, the Committee decided that HBVaxPro's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about HBVaxPro

The European Commission granted a marketing authorisation valid throughout the European Union for HBVaxPro to Sanofi Pasteur MSD SNC on 27 April 2001. The marketing authorisation is valid for an unlimited period.

The full EPAR for HBVaxPro can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with HBVaxPro, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 02-2011.