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EPAR summary for the public

Ambirix

Hepatitis A (inactivated) and hepatitis B (rDNA) (HAB) vaccine (adsorbed)

This is a summary of the European public assessment report (EPAR) for Ambirix. 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 Ambirix.

What is Ambirix?

Ambirix is a vaccine that contains inactivated (killed) hepatitis A virus and parts of the hepatitis B virus as active substances. It is available as a suspension for injection.

What is Ambirix used for?

Ambirix is used to protect against hepatitis A and hepatitis B (diseases that affect the liver) in children between one and 15 years of age who are not already immune to these two diseases.

Ambirix is used as a two-dose schedule and protection against hepatitis B may not be obtained until after the second dose. Because of this, Ambirix should only be used when there is a low risk of hepatitis B infection during the vaccination course, and when it is certain that the two-dose vaccination course can be completed.

The medicine can only be obtained with a prescription.

How is Ambirix used?

Ambirix is given as two injections six to 12 months apart into the muscle of the upper arm, or into the thigh in very young children. Individuals who receive the first injection should complete the course with Ambirix.

Where a booster dose of hepatitis A or B is desired, Ambirix, or a separate hepatitis A or B vaccine may be given.

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How does Ambirix work?

Ambirix is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Ambirix contains small amounts of inactivated hepatitis A viruses and the 'surface antigen' (proteins from the surface) of the hepatitis B virus. When a child is given the vaccine, the immune system recognises the viruses and surface antigens as 'foreign' and makes antibodies against them., The immune system will then be able to make antibodies more quickly when exposed to the viruses again. The antibodies will help to protect against the diseases caused by these viruses.

The vaccine is 'adsorbed'. This means that the viruses and surface antigens are fixed onto aluminium compounds, to stimulate a better response. The surface antigens of the hepatitis B virus 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 active substances in Ambirix have been available in other vaccines authorised in the European Union (EU): Ambirix contains the same ingredients as Twinrix Adult, which has been authorised since 1996, and as Twinrix Paediatric, which has been authorised since 1997. The three vaccines are used to protect against the same diseases, but Twinrix Adult and Twinrix Paediatric are given as a three-dose schedule.

How has Ambirix been studied?

Because Ambirix and Twinrix Adult contain identical ingredients, some of the data used to support the use of Twinrix Adult were used to support the use of Ambirix.

Three main studies of Ambirix were carried out in a total of 615 children from one year of age. All of the children received two doses of Ambirix six months apart. Two of the studies compared Ambirix with other vaccines against hepatitis A and B. The main measure of effectiveness was the proportion of vaccinated children who developed protective levels of antibodies one month after the last injection.

An additional study in 208 children compared the vaccine's effectiveness when a six-month or a 12-month interval was used between the two injections.

What benefit has Ambirix shown during the studies?

Ambirix led to the development of protective levels of antibodies against hepatitis A and B in between 98 and 100% of the vaccinated children one month after the last injection. These levels were maintained in over 93% of the children after two years. Ambirix was as effective as other vaccines against hepatitis A and B once the full vaccination course had been completed. However, full protection against hepatitis B did not develop until the second dose of Ambirix had been given.

The additional study showed that the levels of protection with Ambirix were similar with a six- and a 12-month gap between injections.

What is the risk associated with Ambirix?

The most common side effects with Ambirix (seen in more than one in 10 doses of the vaccine) are loss of appetite, irritability, headache, fatigue (tiredness) and pain and redness at the site of injection. For the full list of all side effects reported with Ambirix, see the package leaflet.

Ambirix should not be used in people who may be hypersensitive (allergic) to any of the active substances, to any of the other ingredients or to neomycin (an antibiotic). It must also not be used in people who have had an allergic reaction after being given hepatitis A or hepatitis B vaccines.

Vaccination with Ambirix should be postponed in patients with a severe sudden fever. The vaccine should never be injected into a vein.

Why has Ambirix been approved?

The CHMP decided that Ambirix's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Ambirix

The European Commission granted a marketing authorisation valid throughout the EU for Ambirix to GlaxoSmithKline Biologicals s.a. on 30 August 2002. After five years, the marketing authorisation was renewed for a further five years.

The full EPAR for Ambirix 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 Ambirix, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2010.