European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

TRITANRIX HEPB

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Tritanrix HepB?
Tritanrix HepB is a vaccine, which is available as a suspension for injection. It contains toxoids (chemically weakened toxins) from diphtheria and tetanus, inactivated (killed) *Bordetella pertussis* (a bacterium that causes whooping cough) and parts of the hepatitis B virus as active substances.

What is Tritanrix HepB used for?
Tritanrix HepB is used to vaccinate infants from six weeks of age against diphtheria, tetanus, pertussis (whooping cough) and hepatitis B.
The medicine can only be obtained with a prescription.

How is Tritanrix HepB used?
Tritanrix HepB is given by deep injection into a muscle, preferably the thigh. The recommended vaccination schedule consists of three doses within the first six months of life, with at least four weeks between each dose. If a vaccine against hepatitis B has not been given at birth, Tritanrix HepB can be given as early as eight weeks of age. In areas where hepatitis B is common, vaccination against hepatitis B at birth should be continued as normal, with Tritanrix HepB started at six weeks of age. A booster dose is recommended before the end of the second year of life.

How does Tritanrix HepB work?
Tritanrix HepB is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against diseases. Tritanrix HepB contains small amounts of:
- toxoids from the bacteria that cause diphtheria and tetanus;
- killed whole *B. pertussis*, the bacterium that causes pertussis;
- 'surface antigen' (proteins from the surface) of the hepatitis B virus.

When an infant is given the vaccine, the immune system recognises the parts of the bacteria and viruses contained in the vaccine 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 bacteria or viruses. This helps to protect against the diseases that these bacteria and viruses cause.
The vaccine is 'adsorbed'. This means that the toxoids and the parts of the hepatitis B virus are fixed onto aluminium compounds, to stimulate a better immune 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.

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The active substances in Tritanrix HepB have been available in the European Union (EU) for a number of years in other vaccines.

How has Tritanrix HepB been studied?
The effects of Tritanrix HepB were first tested in experimental modes before being studied in humans. Tritanrix HepB has been studied in six studies involving a total of 872 infants aged between seven and 20 weeks, all of whom received the vaccine. The main measure of effectiveness was the production of protective antibodies in the infants after the first set of vaccinations.
Further studies looked at the effects of the vaccine in younger infants and at the persistence of antibody levels after vaccination.

What benefit has Tritanrix HepB shown during the studies?
The studies showed that the production of protective levels of antibodies against diphtheria, tetanus and hepatitis B occurred in at least 98% of the infants. At least 92% developed protective levels of antibodies against pertussis.
The additional studies showed that starting vaccination at six weeks was adequate, and that a booster dose is needed in the second year of life in order to maintain protection.

What is the risk associated with Tritanrix HepB?
The most common side effects with Tritanrix HepB (seen in more than 1 in 10 doses of the vaccine) are drowsiness, feeding problems, fever, redness, swelling, pain, unusual crying and irritability. For the full list of all side effects reported with Tritanrix HepB, see the Package Leaflet.
Tritanrix HepB should not be used in infants who may be hypersensitive (allergic) to any of the active substances or any of the other ingredients. It should also not be used in infants who have had an allergic reaction after being given diphtheria, tetanus, pertussis or hepatitis B vaccines. Tritanrix HepB should be postponed in infants with a severe sudden fever, and it should not be given if the child has had encephalopathy (a brain disease) of unknown cause within seven days of a previous vaccination with a vaccine containing pertussis.
As for all vaccines, if Tritanrix HepB is used in very premature babies, there is a risk of the babies experiencing apnoea (brief pauses in breathing). Their breathing should be monitored for up to three days after vaccination.

Why has Tritanrix HepB been approved?
The Committee for Medicinal Products for Human Use (CHMP) decided that Tritanrix HepB's benefits are greater than its risks for active immunisation against diphtheria, tetanus, pertussis and hepatitis B in infants from six weeks onwards. The Committee recommended that Tritanrix HepB be given marketing authorisation.

Other information about Tritanrix HepB:
The European Commission granted a marketing authorisation valid throughout the EU to GlaxoSmithKline Biologicals s.a. for Tritanrix HepB on 19 July 1996. The marketing authorisation was renewed on 19 July 2001 and on 19 July 2006.

The full EPAR for Tritanrix HepB can be found here.

This summary was last updated in 04-2008.