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EPAR summary for the public

Tritanrix HB

Diphtheria, tetanus, pertussis (whole cell) and hepatitis B (rDNA) vaccine (adsorbed)

This is a summary of the European public assessment report (EPAR) for Tritanrix HB. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Tritanrix HB.

For practical information about using Tritanrix HB, patients should read the package leaflet or contact their doctor or pharmacist.

What is Tritanrix HB and what is it used for?

Tritanrix HB is a vaccine containing active substances derived from bacteria that cause diphtheria, tetanus and pertussis, and from the hepatitis B virus. It is used in children aged from six weeks onwards to protect against the following diseases:

- diphtheria (a highly contagious disease that affects the throat and skin, and can cause damage to the heart and other organs);
- tetanus (lockjaw, usually caused by infection of a wound);
- pertussis (whooping cough);
- hepatitis B (a viral liver infection).

How is Tritanrix HB used?

Tritanrix HB can only be obtained with a prescription. It is available as a suspension for injection and 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 HB 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 HB started at six weeks of age.

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A booster dose is recommended before the end of the second year of life.

For further information, see the package leaflet.

How does Tritanrix HB work?

Tritanrix HB is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against diseases. Tritanrix HB contains small amounts of:

- toxoids (chemically inactivated toxins) 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 some of the active substances 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 protein.

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

What benefits of Tritanrix HB have been shown in studies?

Tritanrix HB has been initially investigated in six studies involving a total of 872 infants aged between seven and 20 weeks. The main measure of effectiveness was the production of protective antibodies in the infants after the first set of vaccinations. Protective levels of antibodies against diphtheria, tetanus and hepatitis B occurred in at least 97% of the infants. At least 92% developed protective levels of antibodies against pertussis.

Additional studies looked at the effects of the vaccine in younger infants and at the persistence of antibody levels after vaccination. These studies showed that starting vaccination at six weeks was adequate, and that antibodies persist during the second year but that a booster dose is needed to maintain protection.

What are the risks associated with Tritanrix HB?

The most common side effects with Tritanrix HB (seen with 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 HB, see the package leaflet.

Tritanrix HB must not be used in infants who have had an allergic reaction after being given diphtheria, tetanus, pertussis or hepatitis-B vaccines. Tritanrix HB should be postponed in infants with a severe 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 against pertussis. For the full list of restrictions, see the package leaflet.

Why has Tritanrix HB received a positive scientific opinion?

The Agency's Committee for Medicinal Products for Human Use (CHMP) noted that Tritanrix HB has been shown to produce protective antibody levels against diphtheria, tetanus, pertussis, hepatitis B virus in infants from 6 weeks onwards.

The CHMP concluded that the benefits of the vaccine outweigh its risks and granted a positive scientific opinion.

What measures are being taken to ensure the safe and effective use of Tritanrix HB?

A risk management plan has been developed to ensure that Tritanrix HB is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Tritanrix HB, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

Other information about Tritanrix HB

The CHMP gave a positive opinion on Tritanrix HB on 19 December 2013. This opinion was given as part of its cooperation with the World Health Organization, whereby the CHMP provides opinions on medicines that are not intended for use in the EU but are needed to prevent or treat diseases of major public interest around the world.

The full EPAR and risk management plan summary for Tritanrix HB can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/Medicines for use outside of the EU. For more information about treatment with Tritanrix HB, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 01-2014.