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EPAR summary for the public

Infanrix hexa

diphtheria (D), tetanus (T), pertussis (acellular, component) (PA), hepatitis B (rDNA) (HBV), poliomyelitis (inactivated) (IPV) and *Haemophilus* type b (Hib) conjugate vaccine (adsorbed)

This document is a summary of the European public assessment report (EPAR) for Infanrix hexa. 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 Infanrix hexa.

What is Infanrix hexa?

Infanrix hexa is a vaccine, which is available as a powder and suspension that are made up into a suspension for injection. It contains the following active substances:

- toxoids (chemically weakened toxins) from diphtheria and tetanus;
- parts of *Bordetella pertussis* (*B. pertussis*, a bacterium that causes whooping cough);
- parts of the hepatitis B virus;
- inactivated polioviruses;
- polysaccharides (sugars) from the bacterium *Haemophilus influenzae* type b ('Hib', a bacterium that causes meningitis).

What is Infanrix hexa used for?

Infanrix hexa is used to protect infants under three years of age against diphtheria, tetanus, pertussis (whooping cough), hepatitis B, poliomyelitis (polio) and diseases caused by Hib (such as bacterial meningitis).

The vaccine can only be obtained with a prescription.

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How is Infanrix hexa used?

The recommended vaccination schedule for Infanrix hexa is two or three doses, given at least one month apart, usually within the first six months of life. Infanrix hexa is given by deep injection into a muscle. The site of injection should be alternated for subsequent injections.

A booster dose of Infanrix hexa or a similar vaccine must be given at least six months after the last dose of the initial course. The choice of which vaccine to use depends on official recommendations.

Infanrix hexa can be given to infants who received a hepatitis B vaccine at birth.

How does Infanrix hexa work?

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

- toxoids from the bacteria that cause diphtheria and tetanus;
- toxoids and other proteins purified from *B. pertussis*;
- surface antigen (proteins from the surface) of the hepatitis B virus;
- polioviruses (types 1, 2 and 3) that have been inactivated (killed) so they do not cause any disease;
- polysaccharides extracted from the 'capsules' that surround the Hib bacteria. The polysaccharides are chemically attached (conjugated) to tetanus toxoid as a carrier protein because this improves the response to the vaccine.

When an infant is given the vaccine, the immune system recognises the parts of the bacteria and viruses 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 active substances 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.

Infanrix hexa is a combination of components that have been available in the European Union (EU) in other vaccines: diphtheria, tetanus, pertussis and hepatitis B were available in Infanrix HepB from 1997 until 2005, and diphtheria, tetanus, pertussis, polioviruses and the Hib component are available in other vaccines.

How has Infanrix hexa been studied?

Infanrix hexa has been studied in nine studies, involving a total of almost 5,000 infants aged between six weeks and two years. Over 3,000 of the infants received the first course of vaccination with Infanrix hexa. The effects of Infanrix hexa were compared with those of separate vaccines containing the same active substances. The main measure of effectiveness was the production of protective antibodies in the infants.

An additional five studies looked at the effects of a booster vaccination with Infanrix hexa.

What benefit has Infanrix hexa shown during the studies?

The nine studies showed that the first course of injections with Infanrix hexa was as effective at producing protective levels of antibodies as separate vaccines containing the same active substances. Overall, between 95 and 100% of the infants had antibodies to diphtheria, tetanus, pertussis, hepatitis B virus, polioviruses, and Hib, one month after the first vaccination course.

The additional studies showed that booster vaccinations with Infanrix hexa were as effective as separate vaccines containing the same active substances one month after the booster vaccination.

What is the risk associated with Infanrix hexa?

The most common side effects with Infanrix hexa (seen in more than 1 in 10 doses of the vaccine) are loss of appetite, fever of 38ºC or more, local swelling, pain and redness at the injection site, fatigue (tiredness), abnormal crying, irritability and restlessness. For the full list of all side effects reported with Infanrix hexa, see the package leaflet.

Infanrix hexa should not be used in infants who may be hypersensitive (allergic) to any of the active substances, to any of the other ingredients of the vaccine, or to neomycin and polymyxin (antibiotics). It must not be used in infants who have had an allergic reaction after receiving a vaccine containing diphtheria, tetanus, pertussis, hepatitis B, polio or Hib in the past. Infanrix hexa must not be used in infants who have had encephalopathy (brain disease) of unknown cause within seven days of receiving a vaccine containing pertussis components in the past. Infanrix hexa should be postponed in infants with a severe sudden fever.

As for all vaccines, if Infanrix hexa is used in babies born very prematurely, there is a risk of them experiencing apnoea (brief pauses in breathing). Their breathing should be monitored for up to three days after vaccination.

Why has Infanrix hexa been approved?

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

Other information about Infanrix hexa:

The European Commission granted a marketing authorisation valid throughout the EU for Infanrix hexa to GlaxoSmithKline Biologicals s.a. on 23 October 2000. The marketing authorisation is valid for an unlimited period.

The full EPAR for Infanrix hexa can be found here. For more information about treatment with Infanrix hexa, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 07-2010.