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EPAR summary for the public

Infanrix Penta

diphtheria (D), tetanus (T), pertussis (acellular, component) (PA), hepatitis B (rDNA) (HBV), poliomyelitis (inactivated) (IPV) vaccine (adsorbed)

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

What is Infanrix Penta?

Infanrix Penta is a vaccine, which is available as 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.

What is Infanrix Penta used for?

Infanrix Penta is used to protect infants under three years of age against diphtheria, tetanus, pertussis (whooping cough), hepatitis B and poliomyelitis (polio).

The vaccine can only be obtained with a prescription.

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How is Infanrix Penta used?

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

A booster dose of Infanrix Penta 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 Penta can be given to infants who received a hepatitis B vaccine at birth.

How does Infanrix Penta work?

Infanrix Penta is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against diseases. Infanrix Penta 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 that they do not cause any disease.

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 Penta 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 and polioviruses are available in other vaccines.

How has Infanrix Penta been studied?

Infanrix Penta has been studied in 16 studies looking at the first course of vaccination. The studies involved over 10,000 infants, about three quarters of whom received Infanrix Penta, given according to various time schedules. Infanrix Penta has also been studied in nine studies of booster vaccination involving over 4,000 infants, 714 of whom received Infanrix Penta as a booster. The main measure of effectiveness was the production of antibodies against the active substances after vaccination.

What benefit has Infanrix Penta shown during the studies?

The studies showed that a first course of vaccination with Infanrix Penta led to the development of protective levels of antibodies. After one month, between 86 and 100% of the infants had developed protective levels of antibodies against all of the active substances in Infanrix Penta.

After booster vaccination, there was an increase in the number of infants with protective levels of antibodies against the active substances.

What is the risk associated with Infanrix Penta?

The most common side effects with Infanrix Penta (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 Penta, see the package leaflet.

Infanrix Penta 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 or polio in the past. Infanrix Penta 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 Penta should be postponed in infants with a severe sudden fever.

As for all vaccines, if Infanrix Penta 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 Penta been approved?

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

Other information about Infanrix Penta:

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

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

This summary was last updated in 07-2010.