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

An overview of Infanrix hexa and why it is authorised in the EU

What is Infanrix hexa and what is it used for?

Infanrix hexa is a vaccine used to protect infants from six weeks of age and toddlers against diphtheria, tetanus, pertussis (whooping cough), hepatitis B, poliomyelitis (polio) and diseases such as bacterial meningitis caused by the bacterium *Haemophilus influenzae* type b (Hib).

Infanrix hexa 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 Hib.

How is Infanrix hexa used?

Infanrix hexa is given by deep injection into a muscle. The vaccination schedule for Infanrix hexa is a course of 2 or 3 doses, given at least 1 month apart, according to official recommendations, usually in the first 6 months of life. Subsequent injections should be given in different areas.

A booster dose of Infanrix hexa or a similar vaccine should be given at least 6 months after the last dose of the initial course. The choice of booster vaccine depends on official recommendations.

The vaccine can only be obtained with a prescription. For more information about using Infanrix hexa, see the package leaflet or contact your doctor or pharmacist.

How does Infanrix hexa work?

Infanrix hexa is a vaccine that protects against a range of infections. Vaccines work by 'teaching' the immune system (the body's natural defences) to defend the body against the infections.

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When a child is given the vaccine, the immune system recognises the parts of the bacteria and viruses 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 comes into contact with 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.

What benefits of Infanrix hexa have been shown in studies?

Infanrix hexa has been studied in nine studies, involving a total of almost 5,000 children aged between 6 weeks and 2 years. Over 3,000 of the children received a 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.

Results of the studies taken together showed that a course of injections with Infanrix hexa was as effective at producing protective levels of antibodies as giving separate vaccines containing the same active substances. Overall, between 95 and 100% of the children had antibodies to diphtheria, tetanus, pertussis, hepatitis B virus, polioviruses, and Hib, 1 month after the vaccination course.

An additional five studies looked at the effects of a booster vaccination with Infanrix hexa. These studies showed that booster vaccinations with Infanrix hexa were as effective as giving separate vaccines containing the same active substances 1 month after the booster vaccination.

What is the risk associated with Infanrix hexa?

For the full list of side effects and restrictions with Infanrix hexa, see the package leaflet.

The most common side effects with Infanrix hexa (seen in more than 1 in 10 doses of the vaccine) include swelling, pain and redness at the injection site, loss of appetite, fever of 38°C or higher, sleepiness, abnormal crying, irritability and restlessness.

Infanrix hexa must not be used in infants who are hypersensitive (allergic) to any of the active substances, to any of the other ingredients of the vaccine, or to neomycin and polymyxin (antibiotics) and formaldehyde. It must not be used in infants who have had an allergic reaction to a vaccine containing diphtheria, tetanus, pertussis, hepatitis B, polio or Hib. Infanrix hexa must not be used in infants who have had encephalopathy (brain disease) of unknown cause within 7 days of receiving a pertussis vaccine. Infanrix hexa should be postponed in infants with a severe sudden fever.

Why is Infanrix hexa approved?

Infanrix hexa has been shown to trigger the production of protective levels of antibodies against diphtheria, tetanus, pertussis, hepatitis B virus, polioviruses, and Hib. The side effects of Infanrix hexa are similar to those of other vaccines used to prevent these conditions and are considered acceptable. The European Medicines Agency therefore decided that Infanrix hexa's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Infanrix hexa?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Infanrix hexa have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Infanrix hexa are continuously monitored. Suspected side effects reported with Infanrix hexa are carefully evaluated and any necessary action taken to protect patients.

Other information about Infanrix hexa

Infanrix hexa received a marketing authorisation valid throughout the EU on 23 October 2000.

Further information on Infanrix hexa can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/infanrix-hexa.

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