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EPAR summary for the public

Hexacima

Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and *Haemophilus influenzae* type b conjugate vaccine (adsorbed)

This is a summary of the European public assessment report (EPAR) for Hexacima. 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 Hexacima.

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

What is Hexacima and what is it used for?

Hexacima is a vaccine containing active substances derived from diphtheria, tetanus, pertussis and *Haemophilus influenzae* type b bacteria, the hepatitis B virus, and inactivated polioviruses. It is used in babies and toddlers aged from six weeks to protect against the following infectious 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);
- poliomyelitis (polio, a disease that affects the nerves and can lead to muscle weakness or paralysis);
- invasive diseases (such as meningitis) caused by *H. influenzae* type b bacteria.

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How is Hexacima used?

Hexacima is available as a suspension for injection in vials and prefilled syringes. It can only be obtained with a prescription. Vaccination with Hexacima should be carried out according to official recommendations.

The recommended initial vaccination schedule is either two doses, given two months apart or three doses, given at least one month apart. A booster dose should be given at least six months after the last of these initial doses. Hexacima or an appropriate combination of other vaccines can be used for the booster dose. Hexacima is given by deep injection into a muscle, normally in the upper thigh or the shoulder.

For further information, see the package leaflet.

How does Hexacima work?

Hexacima is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against diseases. Hexacima contains small amounts of materials derived from the bacteria and viruses it protects against. These materials have been inactivated where necessary so that they do not cause any disease.

When a child 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 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 response.

What benefits of Hexacima have been shown in studies?

Hexacima has been studied in several countries worldwide in 12 main studies involving over 3,400 children between six weeks and two years of age who were given three doses of the vaccine during their first six months of life according to different local vaccination schedules. The effects were compared with a combination of separate vaccines designed to protect against the diseases included in Hexacima. The main measure of effectiveness was the production of antibody levels known to be protective against those diseases.

Five of these studies examined the effect of giving a booster dose at least 6 months after the initial vaccination schedule in 1,511 children. The studies showed that protective antibody levels against the various diseases developed in between 90 and 100% of children after the first three doses of Hexacima; protection was maintained or improved when a booster dose was given.

A subsequent study involving 455 children looked at the longer-term persistence of protective antibodies up to 3 years after a booster dose with Hexacima, and another study in 1,336 children evaluated the response to different lots of the vaccine and what happened when it was given with vaccines for infections caused by the bacterium *Streptococcus pneumoniae* (Prevenar) and rotavirus (Rotarix). These studies showed that Hexacima produces similar antibody profiles over time to comparable vaccines, and that the vaccine can be given at the same time as Prevenar and Rotarix.

The two-dose vaccination schedule was investigated in an additional main study involving 554 children. In the study, children who received Hexacima produced a similar antibody response to those who

received a comparator vaccine (Infanrix hexa), when given as a two-dose schedule followed by a booster 6 months later.

What are the risks associated with Hexacima?

The most common side effects with Hexacima include pain and redness at the site of injection, irritability and crying. Reactions may be more likely after the first dose than later doses. For the full list of all side effects reported with Hexacima, see the package leaflet.

Hexacima must not be used in children who have ever had an allergic reaction to Hexacima or a vaccine containing the same components, including substances used during the manufacture of the vaccine and which may be found at extremely low levels (such as the antibiotics neomycin or streptomycin). It must not be used in children who have ever had encephalopathy (a brain disease) of unknown cause within seven days of receiving a vaccine containing pertussis components in the past. It must not be used in children who have an uncontrolled or severe illness affecting the brain or nervous system, such as uncontrolled epilepsy, unless the condition has stabilised with treatment and the benefit clearly outweighs the risk. Vaccination with Hexacima should be postponed if a child has a moderate to severe fever. For the full list of restrictions, see the package leaflet.

Why is Hexacima approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Hexacima's benefits are greater than its risks and recommended that it be approved for use in the EU.

The CHMP noted that Hexacima has been shown to produce protective antibody levels against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and *H. influenzae* type b infections in children between six weeks and two years of age regardless of ethnicity. Although no data are available in children older than 2 years, there is no indication that older children would respond differently.

Regarding safety, the CHMP considered that Hexacima's overall safety profile is similar to other vaccines, although Hexacima is more likely than similar vaccines to cause reactions (mainly at the injection site).

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

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

Other information about Hexacima

The European Commission granted a marketing authorisation valid throughout the European Union for Hexacima on 17 April 2013.

The full EPAR for Hexacima can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Hexacima, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 05-2016.