EMA/410207/2016
EMEA/H/W/002495

EPAR summary for the public

Hexaxim

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 Hexaxim. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion on the medicine and its recommendations on the conditions of use for Hexaxim.

What is Hexaxim?

Hexaxim 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 available as a suspension for injection in vials and prefilled syringes.

What is Hexaxim used for?

Hexaxim is used to protect babies and toddlers from six weeks of age 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.

The vaccine can only be obtained with a prescription.

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How is Hexaxim used?

The recommended initial course for Hexaxim is either two doses, given two months apart or three doses, given at least four weeks apart.

A booster dose should be given at least six months after the last dose of the initial course. Hexaxim or any other appropriate combination of other vaccines can be used as a booster. The choice of which vaccine to use depends on official recommendations.

Hexaxim is given by injection into a muscle, usually the front side of the upper thigh or the shoulder muscle in older children.

How does Hexaxim work?

Hexaxim is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against diseases. Hexaxim 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 the active substances are fixed onto aluminium compounds, to enhance the immune response.

How has Hexaxim been studied?

Hexaxim has been investigated in 12 main studies conducted in four continents, involving children of various ethnicities aged between six weeks and two years. The children received either Hexaxim or a comparator vaccine, with 3,424 children receiving three doses of Hexaxim and 1,511 of them receiving a booster dose. The two-dose vaccination schedule was investigated in an additional main study involving 554 children who either received Hexaxim or a comparator vaccine, when given as a two dose schedule followed by a booster 6 months later.

The studies compared levels of protective antibodies produced following vaccination with Hexaxim with the levels produced following vaccination with comparator vaccines.

What benefit has Hexaxim shown during the studies?

The studies showed that Hexaxim was effective at producing protective levels of antibodies. Overall, between 93 and 100% of the children had protective antibodies levels against the various diseases after the first vaccination course. The studies also showed that booster vaccinations with Hexaxim were effective at maintaining protective antibody levels. In the study investigating Hexaxim given as a two-dose schedule, children given Hexaxim had a similar response to children given a comparator vaccine (Infanrix hexa): 94 to 100% of children receiving Hexaxim had protective antibody levels, compared with 85 to 100% of children who received the comparator vaccine.

What is the risk associated with Hexaxim?

The most common side effects seen with Hexaxim in studies are pain and redness at the injection site, irritability and crying. For the full list of all side effects reported with Hexaxim, see the package leaflet.

Hexaxim must not be used in children who have had an allergic reaction to any pertussis vaccine or to a vaccine containing the same components as Hexaxim.

Hexaxim must not be used in children who have had encephalopathy (a brain disease) of unknown cause within seven days of receiving a vaccine containing pertussis components in the past. Hexaxim must be postponed in children with moderate or severe fever, though it can still be given to children with low grade fever or minor infection.

Hexaxim should not be used in patients with uncontrolled neurologic disorders (affecting the brain) or epilepsy, unless the benefit clearly outweighs the risk. For the full list of restrictions, see the package leaflet.

Why has Hexaxim received a positive scientific opinion?

The CHMP noted that Hexaxim 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.

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 Hexaxim?

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

Other information about Hexaxim

The CHMP gave a positive scientific opinion on Hexaxim on 21 June 2012. This opinion was given as part of the EMA's cooperation with the World Health Organisation, 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 health importance around the world.

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

This summary was last updated in 05-2016.