European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

QUINTANRIX

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Quintanrix?

Quintanrix is a vaccine, which is available as a powder and suspension to be made up into a suspension for injection. It contains the following active substances: toxoids (chemically weakened toxins) from diphtheria and tetanus, inactivated (killed) *Bordetella pertussis* (a bacterium that causes whooping cough), parts of the hepatitis B virus and polysaccharides (sugars) from the bacterium *Haemophilus influenzae* type b ('Hib', a bacterium that causes meningitis).

What is Quintanrix used for?

Quintanrix is used to vaccinate infants under one year of age against diphtheria, tetanus, pertussis (whooping cough), hepatitis B and 'invasive' diseases caused by Hib (such as bacterial meningitis). It is also used as a booster immunisation of young children during the second year of life. It should be used according to official recommendations.
The medicine can only be obtained with a prescription.

How is Quintanrix used?

The recommended vaccination schedule for Quintanrix is three doses, given at intervals of at least four weeks within the first six months of life. The first dose can be administered at six weeks of age. The vaccine is given by deep injection into a muscle, preferably the thigh.
After the first vaccination course, a booster should be given, preferably before the end of the second year of life. Quintanrix can also be used to boost previous vaccinations against diphtheria, tetanus and pertussis, against hepatitis B or against Hib, when it should be given at least six months after the last dose of the first vaccination course.
Quintanrix can be given to children who received a hepatitis B vaccine at birth.

How does Quintanrix work?

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

- toxoids from the bacteria that cause diphtheria and tetanus;
- killed whole *B. pertussis*;
- polysaccharides extracted from the 'capsules' that surround the bacterium Hib - the polysaccharides are chemically attached (conjugated) to tetanus toxoid as a carrier protein because this improves the response to the vaccine;

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- ‘surface antigen’ (proteins from the surface) of the hepatitis B virus.

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 on aluminium compounds, to stimulate a better immune 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.

The active substances in Quintanrix have been available in the European Union (EU) for a number of years in other vaccines: diphtheria, tetanus, pertussis and hepatitis B, has been available in Tritanrix HepB since 1996. These active substances were also available in other vaccines before that date. The Hib component has also been available in other vaccines.

How has Quintanrix been studied?

The effects of Quintanrix have been studied in five main studies involving over 2,000 infants. In three studies, the effects of Quintarix were compared with those of the combination of Tritanrix HepB and a vaccine containing Hib: two of these studies involved a total of 1,208 infants who were vaccinated at two, four and six months of age and one involved 294 infants vaccinated at three, four and five months of age. The fourth study compared the effects of Quintarix given at six, 10 and 14 weeks of age in 318 infants who either had or had not received a hepatitis B vaccine at birth. The fifth study looked at the effects of a fourth, booster dose of Quintanrix in the second year of life in 357 infants. In all of the studies, the main measure of effectiveness was the production of protective levels of antibodies after the final vaccination.

What benefit has Quintanrix shown during the studies?

Quintarix was as effective as the two separate vaccines at producing protective levels of antibodies. Overall, between 95 and 100% of the infants had protective levels of antibodies to diphtheria, tetanus, pertussis, hepatitis B and Hib, one month after the first vaccination course. There was no impact of prior hepatitis B vaccination on the effectiveness of Quintanrix.

The study of booster vaccination also showed Quintanrix was as effective as the two separate vaccines, with between 92 and 100% of the infants having protective levels of antibodies 42 days after the booster vaccination.

What is the risk associated with Quintanrix?

The most common side effects with Quintanrix (seen in more than 1 in 10 doses of the vaccine) are irritability, drowsiness, loss of appetite, pain, redness and swelling, and fever. For the full list of side effects reported with Quintanrix, see the Package Leaflet.

Quintanrix should not be used in people who may be hypersensitive (allergic) to any of the active substances or any of the other ingredients. It should not be given if the child has had encephalopathy (a brain disease) of unknown cause within seven days of a previous vaccination with a vaccine containing pertussis. Quintanrix should be postponed in people with a severe sudden fever.

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

Why has Quintanrix been approved?

The Committee for Medicinal Products for Human Use (CHMP) decided that Quintanrix’s benefits are greater than its risks for primary immunisation of infants (during the first year of life) against diphtheria, tetanus, pertussis, hepatitis B and invasive disease caused by Hib and for booster immunisation of young children during the second year of life. The Committee recommended that Quintanrix be given marketing authorisation.

Other information about Quintanrix:

The European Commission granted a marketing authorisation valid throughout the EU for Quintanrix to GlaxoSmithKline Biologicals s.a. on 21 October 2004.

The full EPAR for Quintanrix can be found here.

This summary was last updated in 04-2008.