European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

TWINRIX PAEDIATRIC

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 Twinrix Paediatric?
Twinrix Paediatric is a vaccine, which is available as a suspension for injection. It contains inactivated (killed) hepatitis A viruses and parts of the hepatitis B virus as active substances. It is available in a 0.5 ml vial and in a 0.5 ml prefilled syringe.

What is Twinrix Paediatric used for?
Twinrix Paediatric is used to protect against hepatitis A and hepatitis B infection (diseases that affect the liver). It is used in infants, children and adolescents aged between one and 15 years who are not already immune to these two diseases and who are at risk of contracting both of them.
The medicine can only be obtained with a prescription.

How is Twinrix Paediatric used?
The recommended vaccination schedule for Twinrix Paediatric is three doses with a gap of one month between the first two doses and a gap of five months between the second and third. It should be given by injection into the muscle of the upper arm or the thigh.
It is recommended that individuals who receive the first dose should complete all three doses of Twinrix Paediatric.
A booster dose of Twinrix Paediatric, or of a separate hepatitis A or B vaccine may be given, according to official recommendations.

How does Twinrix Paediatric work?
Twinrix Paediatric is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Twinrix Paediatric contains small amounts of inactivated hepatitis A viruses and the 'surface antigen' (proteins from the surface) of the hepatitis B virus. When a person is given the vaccine, the immune system recognises the viruses and surface antigens as 'foreign' and makes antibodies against them. In the future, the immune system will be able to make antibodies more quickly when it is exposed to the viruses. The antibodies will help to protect against diseases caused by these viruses.
The vaccine is 'adsorbed'. This means that the viruses and surface antigens 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.

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Twinrix Paediatric is identical to the vaccine Twinrix Adult, which has been available in the European Union (EU) since 1996. The only difference between the two vaccines is the amount of vaccine in each vial or syringe. The active substances in Twinrix Paediatric and Twinrix Adult have been available in the EU for a number of years in separate vaccines: Havrix Adult for protection against hepatitis A and Engerix-B for protection against hepatitis B.

How has Twinrix Paediatric been studied?
Because Twinrix Paediatric and Twinrix Adult contain identical ingredients, some of the data used to support the use of Twinrix Adult were used to support the use of Twinrix Paediatric.
Two studies were carried out in a total of 180 children and adolescents, all of whom received Twinrix Paediatric. The main measure of effectiveness was the proportion of the children who had developed protective levels of antibodies to hepatitis A and hepatitis B.
Further studies looked at the persistence of antibody levels after vaccination.

What benefit has Twinrix Paediatric shown during the studies?
The studies showed that Twinrix Paediatric produced an immune response that was at least as good as that seen during studies of Twinrix Adult. All children had satisfactory antibody levels to hepatitis A by two months, and almost 100% had protective levels of antibodies to hepatitis B by six months (just before the third vaccine dose). Levels of antibodies to both hepatitis A and B increased after the third dose of the vaccine.
The additional studies showed that the presence of antibodies was maintained for at least four years.

What is the risk associated with Twinrix Paediatric?
The most common side effect with Twinrix Paediatric (seen in more than 1 in 10 doses of the vaccine) is pain and redness at the injection site. For the full list of all side effects reported with Twinrix Paediatric, see the Package Leaflet.
Twinrix Paediatric should not be used in people who may be hypersensitive (allergic) to any of the active substances, to any of the other ingredients or to neomycin (an antibiotic). It should also not be used in people who have had an allergic reaction after being given hepatitis A or hepatitis B vaccines. Twinrix Paediatric should be postponed in patients with a severe sudden fever. It should never be injected into a vein.

Why has Twinrix Paediatric been approved?
The Committee for Medicinal Products for Human Use (CHMP) decided that Twinrix Paediatric's benefits are greater than its risks for use in non-immune infants, children and adolescents from one year up to and including 15 years who are at risk of both hepatitis A and hepatitis B infection. The Committee recommended that Twinrix Paediatric be given marketing authorisation.

Other information about Twinrix Paediatric:
The European Commission granted a marketing authorisation valid throughout the EU to GlaxoSmithKline Biologicals s.a. for Twinrix Paediatric on 10 February 1997. The marketing authorisation was renewed on 10 February 2002 and on 10 February 2007.

The full EPAR for Twinrix Paediatric can be found here.

This summary was last updated in 02-2008.