European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

TWINRIX ADULT

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 Adult?

Twinrix Adult 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 1 ml vial and in a 1 ml prefilled syringe.

What is Twinrix Adult used for?

Twinrix Adult is used to protect against hepatitis A and hepatitis B infection (diseases that affect the liver). It is used in adults and adolescents from 16 years of age 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 Adult used?

The recommended vaccination schedule for Twinrix Adult 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. The vaccine is injected into the muscle of the upper arm.
In exceptional cases, the three injections can be given over three weeks for adults needing rapid protection before travelling. In these cases, a fourth injection is recommended 12 months after the first dose.
It is recommended that individuals who receive the first dose should complete all doses of Twinrix Adult. A booster dose of Twinrix Adult, or of a separate hepatitis A or B vaccine may be given, according to official recommendations.

How does Twinrix Adult work?

Twinrix Adult is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Twinrix Adult 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. If exposed to the viruses in the future, the immune system will be able to make antibodies more quickly. 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

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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 Twinrix Adult have been available in the European Union (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 Adult been studied?
Twinrix Adult has been studied in three main studies involving 843 healthy people aged between 18 and 60 years, most of whom were under 40 years of age. Each person received Twinrix Adult doses at months 0, 1 and 6. The main measure of effectiveness was the proportion of the people who had developed antibodies against hepatitis A and B.
Further studies looked at the persistence of antibodies after vaccination in adults and adolescents, and at the schedule for vaccinating adults over three weeks when rapid protection is required.

What benefit has Twinrix Adult shown during the studies?
The studies showed that for hepatitis A, antibodies were detected in 94% of adults after the first dose, 99.5% after the second dose and 100% after the third dose. For hepatitis B, antibodies were detected in 71% of adults after the first dose, 97% after the second dose and 99.7% after the third dose.
The additional studies showed that the presence of antibodies was maintained for up to five years. The three-week vaccination schedule also led to the production of antibodies in around 83% of patients, rising to around 89% after the booster dose at month 12.

What is the risk associated with Twinrix Adult?
The most common side effects with Twinrix Adult (seen in more than 1 in 10 doses of the vaccine) are headache, pain and redness at the injection site, and fatigue (tiredness). For the full list of all side effects reported with Twinrix Adult, see the Package Leaflet.
Twinrix Adult 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 Adult should be postponed in patients with a severe sudden fever. It should never be injected into a vein.

Why has Twinrix Adult been approved?
The Committee for Medicinal Products for Human Use (CHMP) decided that Twinrix Adult’s benefits are greater than its risks for use in non-immune adults and adolescents of 16 years of age and above who are at risk of both hepatitis A and hepatitis B infection. The Committee recommended that Twinrix Adult be given marketing authorisation.

Other information about Twinrix Adult:
The European Commission granted a marketing authorisation valid throughout the EU to GlaxoSmithKline Biologicals s.a. for Twinrix Adult on 20 September 1996. The marketing authorisation was renewed on 20 September 2001 and on 20 September 2006.

The full EPAR for Twinrix Adult can be found here.

This summary was last updated in 02-2008.