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EPAR summary for the public

Adjupanrix

Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted)

This is a summary of the European public assessment report (EPAR) for Adjupanrix. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Adjupanrix.

What is Adjupanrix?

Adjupanrix is a vaccine that is given by injection. It contains parts of influenza (flu) viruses that have been inactivated (killed). The vaccine contains a flu strain called 'A/VietNam/1194/2004 NIBRG 14' (H5N1).

This vaccine is the same as the Pandemrix H5N1 mock-up vaccine, which was previously authorised in the European Union (EU). The company that made the Pandemrix H5N1 mock-up vaccine has agreed that its scientific data can be used for this vaccine.

What is this vaccine used for?

Adjupanrix is a vaccine for use in adults to protect against 'pandemic' flu. It should only be used once a flu pandemic has been officially declared by the World Health Organization (WHO) or European Union (EU). A flu pandemic happens when a new strain of flu virus appears that can spread easily from person to person because people have no immunity (protection) against it. A pandemic can affect most countries and regions around the world. The vaccine would be given according to official recommendations.

The vaccine can only be obtained with a prescription.

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How is this vaccine used?

The vaccine is given by injection into the shoulder or thigh muscle. People who have not previously been vaccinated against the pandemic flu with a 'prepandemic' vaccine should receive two single 0.5 ml doses of the vaccine at least three weeks apart. Adults over 80 years of age may need a double dose of the vaccine (one injection into each shoulder) with a second double dose three weeks later. People who have previously been vaccinated with a prepandemic vaccine that contains a similar flu strain to the one causing the pandemic will only need one single dose.

There are some data supporting the use of half-doses (0.25 ml) in children three to nine years of age.

How does this vaccine work?

Adjupanrix is a 'mock-up' vaccine. This is a special type of vaccine that can be developed to help with the management of a future pandemic.

Before a pandemic starts, nobody knows which strain of flu virus will be involved, so pharmaceutical companies cannot prepare the correct vaccine in advance. Instead, they can prepare a vaccine that contains a strain of flu virus specifically chosen because very few people have been exposed to it, and to which very few people are immune. They can then test this vaccine to see how people react to it, allowing them to predict how people will react when the flu strain causing the pandemic is included.

Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. This vaccine contains small amounts of haemagglutinins (proteins from the surface) of a virus called H5N1. The virus has first been inactivated so that it does not cause any disease. During a pandemic, the virus strain in the vaccine will have to be replaced by the strain causing the pandemic before the vaccine can be used.

When a person is given the vaccine, the immune system recognises the virus as 'foreign' and makes antibodies against it. The immune system will then be able to produce antibodies more quickly when it is exposed to the virus again. This will help to protect against the disease caused by the virus.

Before use, the vaccine will be made up by mixing together a suspension that contains the virus particles with a solvent. The resulting 'emulsion' will then be injected. The solvent contains an 'adjuvant' (a compound containing oil) to enhance the immune response.

How has this vaccine been studied?

The main study of the vaccine included 400 healthy adults aged between 18 and 60 years and compared the ability of different doses of the vaccine, with or without the adjuvant, to trigger the production of antibodies ('immunogenicity'). The participants received two injections of the vaccine containing one of four different doses of haemagglutinin. The injections were given 21 days apart. The main measures of effectiveness were the levels of antibodies against the flu virus in the blood at three different times: before vaccination, on the day of the second injection (day 21) and 21 days later (day 42). A further study looked at the immunogenicity of single or double doses in 437 people aged over 60 years, and two studies looked at the effect of giving a single injection of the vaccine to adults who had previously been vaccinated with a prepandemic vaccine containing a related virus strain.

A study in 405 children three to nine years of age looked at the immunogenicity triggered by a vaccine containing half the amount of haemagglutinins compared with the vaccine containing the full amount.

What benefit has this vaccine shown during the studies?

According to criteria laid down by the CHMP, a mock-up vaccine needs to bring about protective levels of antibodies in at least 70% of people for it to be considered suitable.

The main study showed that the 3.75 microgram dose of the adjuvanted vaccine produced an antibody response that met these criteria. At 21 days after the second injection, 84% of the people receiving the vaccine had levels of antibodies that would protect them against H5N1.

In elderly people, single doses also met the CHMP's criteria, except for in the small number of patients aged over 80 years who did not have any protection against the virus at the start of the study. These patients needed double doses of the vaccine for protection.

The final two studies in adults showed that a single dose of the vaccine was sufficient to bring about protective levels of antibodies in people who had previously been vaccinated with a prepandemic vaccine containing a related flu strain.

In children aged three to nine years, the half-dose vaccine was shown bring about levels of antibodies that were comparable with the full-dose vaccine.

What is the risk associated with this vaccine?

The most common side effects with the vaccine (seen with more than 1 in 10 doses of the vaccine) are headache, arthralgia (joint pain), myalgia (muscle pain), reactions at the site of the injection (hardening, swelling, pain and redness), fever and fatigue (tiredness). For the full list of all side effects reported with this vaccine, see the package leaflet.

The vaccine must not be given to people who have had an anaphylactic reaction (severe allergic reaction) to any of the components of the vaccine, or to any of the substances found at very low levels in the vaccine, such as eggs, chicken protein, ovalbumin (a protein in egg white), formaldehyde, gentamicin sulphate (an antibiotic) and sodium deoxycholate. If a pandemic has started, however, it may be appropriate to give the vaccine to these patients, as long as facilities for resuscitation are available.

Why has Adjupanrix been approved?

The CHMP decided that the vaccine's benefits are greater than its risks and recommended that it be given marketing authorisation.

The vaccine has been authorised under 'exceptional circumstances'. This means that, because the vaccine is a mock up and does not yet contain the strain of flu virus that is causing a pandemic, it has not been possible to obtain full information about the final pandemic vaccine. Every year, the European Medicines Agency will review any new information that may become available and this summary will be updated as necessary.

What information is still awaited?

When the company that makes the vaccine includes the flu strain responsible for a pandemic in the vaccine, it will collect information on the safety and effectiveness of the final pandemic vaccine, and submit this to the CHMP for evaluation.

Other information about Adjupanrix

The European Commission granted a marketing authorisation valid throughout the European Union for Adjupanrix on 19 October 2009.

The full EPAR for Adjupanrix 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 this vaccine, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2012.