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EPAR summary for the public

Prepandrix

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

This is a summary of the European public assessment report (EPAR) for Prepandrix. 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 Prepandrix.

What is Prepandrix?

Prepandrix is a vaccine that is given by injection. It contains parts of influenza (flu) viruses that have been inactivated (killed). Prepandrix contains a flu strain called 'A/Indonesia/05/2005' (H5N1).

What is Prepandrix used for?

Prepandrix is a vaccine for use in adults to protect against flu caused by the H5N1 strain (type) of the influenza A virus. Prepandrix is given according to official recommendations.

The vaccine can only be obtained with a prescription.

How is Prepandrix used?

Prepandrix is given by injection into the shoulder or thigh as two 0.5 ml doses, at least three weeks apart. Adults over 80 years of age may need a double dose of the vaccine (one injection into each shoulder).

There are some data with a vaccine containing a similar H5N1 strain that support the use of half-doses (0.25 ml) in children three to nine years of age.

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How does Prepandrix work?

Prepandrix is a 'prepandemic' vaccine. This is a special type of vaccine that is intended to protect against a strain of flu that may cause a future pandemic. 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. Health experts are concerned that a future flu pandemic could be caused by the H5N1 strain of the virus. Prepandrix has been developed to provide protection against this strain, so that it can be used before or during a flu pandemic.

Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Prepandrix contains small amounts of haemagglutinins (proteins from the surface) of the H5N1 virus. The virus has first been inactivated (killed) so that it does not cause any disease. 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 may help to protect against the disease caused by the virus.

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

How has Prepandrix been studied?

The main study of Prepandrix included 675 healthy adults and compared the ability of Prepandrix, with or without the adjuvant, to trigger the production of antibodies ('immunogenicity'). The participants received two injections of Prepandrix 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).

An additional study was also used to support the main study and to demonstrate the vaccine's safety.

What benefit has Prepandrix shown during the studies?

According to criteria laid down by the CHMP, a prepandemic 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 Prepandrix containing the adjuvant produced an antibody response that met these criteria. At 21 days after the second injection, over 90% of the people receiving the vaccine had levels of antibodies that would protect them against H5N1.

What is the risk associated with Prepandrix?

The most common side effects with Prepandrix (seen in more than 1 patient in 10) 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 Prepandrix, see the package leaflet.

Prepandrix must not be given to people who are hypersensitive (allergic) to any of the components of the vaccine, or to any of the substances found at trace (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. Vaccination with Prepandrix should be delayed in people who have a severe fever or a sudden infection.

Why has Prepandrix been approved?

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

Other information about Prepandrix

The European Commission granted a marketing authorisation valid throughout the European Union for Prepandrix on 14 May 2008.

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

This summary was last updated in 12-2012.