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EPAR summary for the public

Pumarix

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

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

What is Pumarix?

Pumarix 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/Indonesia/05/2005 PR8-IBCDC-RG2' (H5N1).

What is Pumarix used for?

Pumarix is a vaccine 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 should be given according to official recommendations.

The vaccine can only be obtained with a prescription.

How is Pumarix used?

The vaccine is given by injection into muscle, preferably into shoulder or thigh muscle. Dosing recommendations are only available for adults. Adults should be given a dose of 0.5 ml followed by a second dose after an interval of at least three weeks. People who have previously been vaccinated with a vaccine that contains the same adjuvant (a substance added to enhance the immune response) and a flu strain similar to the one causing the pandemic will only need one single dose.

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How does Pumarix work?

Pumarix 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 an emulsion. The emulsion contains the 'adjuvant' to enhance the immune response.

How has Pumarix been studied?

The effects of Pumarix were first tested in experimental models before being studied in humans.

One main study involving 680 adults compared Pumarix given as two doses three weeks apart with Pandemrix H5N1 (another pandemic influenza vaccine) and also compared Pumarix given with and without an adjuvant. In the second main study, 4,560 adults were given either Pumarix or placebo (a dummy vaccine). The main measure of effectiveness in both studies was the ability to trigger the production of antibodies against the flu virus ('immunogenicity') after six weeks.

What benefit has Pumarix shown during the studies?

In the first study, the immunogenicity of Pumarix was shown to be comparable to that of the comparator vaccine. The study also showed that Pumarix triggered the production of more antibodies when given with an adjuvant than when given without. The second study showed that Pumarix was able to trigger the production of antibodies to a level high enough to meet CHMP criteria.

What is the risk associated with Pumarix?

The most common side effects with Pumarix (seen in more than 1 patient in 10) are headache, joint pain, muscle ache, pain at injection site and fatigue (tiredness).

Pumarix should 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 trace levels in the vaccine, such as egg or chicken protein, ovalbumin (a protein in egg white), formaldehyde and sodium deoxycholate. However, it may be appropriate to give the vaccine to these patients during a pandemic, as long as facilities for resuscitation are available.

Why has Pumarix 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 for Pumarix?

When the company that makes the vaccine includes in it the flu strain responsible for a pandemic, 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 Pumarix

The European Commission granted a marketing authorisation valid throughout the European Union for Pumarix to GlaxoSmithKline Biologicals s.a. on 4 March 2011. The marketing authorisation is valid for five years, after which it can be renewed.

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

This summary was last updated in 12-2010.