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EPAR summary for the public

Humenza

Pandemic influenza vaccine (H1N1) (split virion, inactivated, adjuvanted)

This document is a summary of the European Public Assessment Report (EPAR) for Humenza. 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 Humenza.

What is Humenza?

Humenza is a vaccine that is given by injection. It contains parts of influenza (flu) viruses that have been inactivated (killed). Humenza contains a flu strain called A/California/7/2009 (H1N1)-like strain (NYMC X-179A).

What is Humenza used for?

Humenza is a vaccine to protect against 'pandemic' flu. It should only be used for the influenza A (H1N1) flu pandemic that was officially declared by the World Health Organization on 11 June 2009. 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. Humenza is given according to official recommendations.

The vaccine can only be obtained with a prescription.

How is Humenza used?

Humenza is given as one dose, injected into the upper arm or thigh muscle. A second dose may be given after an interval of at least three weeks, particularly in children from six months to three years of age. This second dose must be given to patients over 60 years of age.

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How does Humenza work?

Humenza is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Humenza contains small amounts of haemagglutinins (proteins from the surface) of a virus called A(H1N1)v that is causing the current pandemic. The virus has first been inactivated 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 will 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 a solvent. The resulting 'emulsion' is then injected. The solvent contains an 'adjuvant' (a compound containing oil) to enhance the immune response.

How has Humenza been studied?

Three studies are being carried out with Humenza containing the H1N1 strain, one in 300 adults and 150 elderly patients (over 60 years of age), and two in a total of 700 children aged between six months and 17 years of age. These studies are looking at the ability of Humenza to trigger the production of antibodies ('immunogenicity') against the H1N1 flu strain. These studies are still ongoing.

The company also presented information from studies in 641 adults carried out using an earlier version of Humenza, containing a 'bird flu' strain H5N1.

What benefit has Humenza shown during the studies?

Preliminary results from the three ongoing studies show that one dose of Humenza was able to trigger immunity to a satisfactory level in adults and children. The percentage of subjects who had a level of antibodies in their blood that was high enough to neutralise the H1N1 virus (seroprotection rate) was 100% in children and close to 100% in adults. The seroprotection rates in elderly subjects were lower but a second dose was shown to bring about a further response.

What is the risk associated with Humenza?

The most common side effects with Humenza (seen with more than 1 in 10 doses of the vaccine) are headache, myalgia (muscle pain) and pain at the site of injection. For the full list of all side effects reported with Humenza, see the Package Leaflet.

Humenza 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 ovalbumin (a protein in egg white), egg or chicken proteins, neomycin, octoxinol-9 and formaldehyde. 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 Humenza been approved?

The Committee decided that Humenza's benefits are greater than its risks for the prophylaxis of influenza in the officially declared H1N1 pandemic situation and recommended that it be given marketing authorisation.

Humenza has been given 'Conditional Approval'. This means that there is more evidence to come about the medicine, in particular the results of further clinical studies in children, adolescents and adults.

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 Humenza?

The company that makes Humenza will supply further data on the medicine, in particular on its safety from a study in 3,000 subjects.

Which measures are being taken to ensure the safe use of Humenza?

The company that makes Humenza will collect information on the safety of the vaccine while it is being used. This will include information on its side effects and its safety in children, the elderly, pregnant women, patients with severe conditions and people who have problems with their immune systems.

Other information about Humenza:

The European Commission granted a marketing authorisation valid throughout the European Union for Humenza to Sanofi Pasteur SA on 08 June 2010. The marketing authorisation is valid for five years, after which it can be renewed.

The full EPAR for Humenza can be found here.

This summary was last updated in 06-2010.