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**EPAR summary for the public**

# Arepanrix

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



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

## What is Arepanrix?

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

## What is Arepanrix used for?

Arepanrix 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. Arepanrix is given according to official recommendations.

The vaccine can only be obtained with a prescription.

## How is Arepanrix used?

Arepanrix is given as one dose, injected into the shoulder muscle. A second dose may be given after an interval of at least three weeks, particularly in children from six months to nine years of age.

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## How does Arepanrix work?

Arepanrix is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Arepanrix 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.

Arepanrix is very similar to another pandemic vaccine called Pandemrix, which has been available in the European Union (EU) since September 2009. Both contain the same adjuvant. In Arepanrix, a different method is used to prepare the haemagglutinins used in the vaccine.



## How has Arepanrix been studied?

The company presented information from studies carried out with an earlier version of Arepanrix, containing the 'bird flu' strain H5N1. This included one study in 4,561 adults, which looked at the ability of Arepanrix H5N1 to trigger the production of antibodies ('immunogenicity') against this H5N1 strain, and one study comparing it with Pandemrix H5N1. A further study compared Arepanrix containing the pandemic flu strain H1N1 with Pandemrix H1N1 in 334 adults. This study looked at the immunogenicity against influenza A(H1N1)v.

Because Arepanrix is similar to Pandemrix, the company used the data on the use of Pandemrix in children to support the use of Arepanrix in children.

## What benefit has Arepanrix shown during the studies?

The studies of Arepanrix H5N1 showed that the vaccine was able to bring about protective levels of antibodies in at least 70% of people in which it was studied. In line with the criteria laid down by the CHMP, this demonstrated that the vaccine brought about an appropriate level of protection. The same level of protection was obtained with Arepanrix as with Pandemrix.

The study comparing Arepanrix H1N1 with Pandemrix H1N1 showed that one dose was able to trigger immunity to a satisfactory level. 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%.

## What is the risk associated with Arepanrix?

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

Arepanrix 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 Arepanrix been approved?

The CHMP noted that Arepanrix had already been marketed in Canada and used to vaccinate over 5 million people with no safety concerns. The Committee decided that Arepanrix'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.

Arepanrix 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 Arepanrix?

The company that makes Arepanrix will provide data collected in clinical trials of Arepanrix in adults and children, as well as information collected on the safety and effectiveness of the vaccine, to the CHMP for evaluation.

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

The company that makes Arepanrix 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 Arepanrix:

The European Commission granted a marketing authorisation valid throughout the European Union for Arepanrix to GlaxoSmithKline Biologicals s.a. on on 23 March 2010.

The full EPAR for Arepanrix can be found here. For more information about treatment with Arepanrix, read the Package Leaflet (also part of the EPAR).

This summary was last updated in 02-2010.