

Celvapan
pandemic influenza vaccine (whole virion, Vero cell derived, inactivated)
A/California/7/2009 (H1N1)

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.

If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Celvapan?

Celvapan is a vaccine that is given by injection. It contains influenza (flu) viruses that have been inactivated (killed). Celvapan contains a flu strain called A/California/07/2009 (H1N1)v.

What is Celvapan used for?

Celvapan is a vaccine to protect against 'pandemic' flu. It should only be used for the influenza A (H1N1) 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. Celvapan is given according to official recommendations. The vaccine can only be obtained with a prescription.

How is Celvapan used?

Celvapan is given by injection into the shoulder muscle in two doses, at least three weeks apart.

How does Celvapan work?

Celvapan is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Celvapan contains a virus called A(H1N1)v that is causing the current pandemic. The virus has been inactivated so that it does not cause any disease.

When a person is given the vaccine, the immune system recognises the inactivated 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 helps to protect against the disease.

The viruses used in Celvapan are grown in mammal cells ('vero cells'), unlike those in some other flu vaccines, which are grown in hen's eggs.

How has Celvapan been studied?

Celvapan was first developed as a 'mock-up' vaccine that contained an H5N1 strain of the flu virus called A/Vietnam/1203/2004. The company studied the ability of this mock-up vaccine to trigger the production of antibodies ('immunogenicity') against this strain of flu virus in advance of the pandemic.

Following the start of the current pandemic, the company replaced the virus strain in Celvapan with the H1N1 strain causing the pandemic, and presented data relating to this change to the Committee for Medicinal Products for Human Use (CHMP).

What benefit has Celvapan shown during the studies?

The mock-up vaccine was shown to bring about protective levels of antibodies in at least 70% of the 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 CHMP was also satisfied that the change of strain to the H1N1 strain did not affect the characteristics of the vaccine.

What is the risk associated with Celvapan?

The most common side effect with Celvapan (seen in more than 1 people vaccinated in 10) is pain at the site of the injection. For the full list of all side effects reported with Celvapan, see the Package Leaflet.

Celvapan 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 (very low) levels in the vaccine, such as formaldehyde, benzonase or sucrose. 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 Celvapan been approved?

The CHMP decided that, based on the information obtained with the mock-up vaccine and the information provided on the strain change, the benefits of Celvapan are greater than its risks for the prophylaxis of influenza in the officially declared H1N1 pandemic situation. The Committee recommended that Celvapan be given marketing authorisation.

Celvapan has been authorised under 'Exceptional Circumstances'. This means that it has not yet been possible to obtain full information about the 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 Celvapan?

The company that makes Celvapan will collect information on the safety and effectiveness of the vaccine, and submit this to the CHMP for evaluation.

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

The company that makes Celvapan 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 Celvapan:

The European Commission granted a marketing authorisation valid throughout the EU for the H5N1 mock-up vaccine for Celvapan to Baxter AG on 4 March 2009. The positive opinion for the H1N1 vaccine was issued on 1 October 2009.

The full EPAR for Celvapan with the most up-to-date information on how the vaccine can be used can be found [here](#).

This summary was last updated in 10-2009.