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EPAR summary for the public

Celvapan

influenza vaccine (H1N1)v (whole virion, Vero cell derived, inactivated)

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

What is Celvapan?

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

What is Celvapan used for?

Celvapan is a vaccine to protect against flu caused by the A (H1N1)v 2009 virus. Celvapan is given according to official recommendations.

The medicine can only be obtained with a prescription.

How is Celvapan used?

Celvapan is given by injection into the muscle of the shoulder or thigh, as 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 2009. The virus has been inactivated (killed) so that it does not cause any disease.

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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'), as opposed to hen's eggs.

How has Celvapan been studied?

Celvapan was originally developed as a pandemic vaccine, to be used during the influenza A (H1N1) pandemic declared in June 2009. Two main studies have been carried out that looked at the ability of two doses of Celvapan H1N1 given three weeks apart to trigger an immune response. One study involved 408 healthy adults, half of whom were over 60 years of age (202 received a full dose of Celvapan, the others a half dose) and the second involved 167 healthy children aged between six months and 17 years (101 received a full dose of Celvapan, the others a half dose).

What benefit has Celvapan shown during the studies?

In both studies, the full dose of the vaccine was shown to bring about protective levels of antibodies to a satisfactory level in line with the criteria laid down by the CHMP.

What is the risk associated with Celvapan?

The most common side effects with Celvapan (seen in more than 1 people vaccinated in 10) are headache and fatigue (tiredness). For the full list of all side effects reported with Celvapan, see the package leaflet.

Celvapan must 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.

Why has Celvapan been approved?

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

What measures are being taken to ensure the safe and effective use of Celvapan?

A risk management plan has been developed to ensure that Celvapan is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Celvapan, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Celvapan:

The European Commission granted a marketing authorisation valid throughout the European Union for Celvapan on 4 March 2009.

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

This summary was last updated in 03-2015.