EMA/388182/2016
EMEA/H/C/000832

EPAR summary for the public

Pandemrix

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

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

What is Pandemrix?

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

What is Pandemrix used for?

Pandemrix is a vaccine to protect against flu caused by the A (H1N1)v 2009 virus. It should only be used if the recommended annual seasonal trivalent/quadrivalent influenza vaccine is not available and if immunisation against (H1N1)v is considered necessary. Pandemrix is given according to official recommendations.

The vaccine can only be obtained with a prescription.

How is Pandemrix used?

Pandemrix is given as one dose, injected into the muscle of the shoulder or thigh. A second dose may be given after an interval of at least three weeks. From 10 years of age the dose is 0.5 ml; younger children aged from six months to nine years receive 0.25 ml per dose.

How does Pandemrix work?

Pandemrix is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Pandemrix contains small amounts of haemagglutinins (proteins

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from the surface) of a virus called A(H1N1)v 2009. The virus has first been inactivated (killed) 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 Pandemrix been studied?

Pandemrix was originally developed as a pandemic vaccine, and was used during the influenza A (H1N1) pandemic declared in June 2009. Six main studies have been carried out that looked at the ability of a two-dose schedule of the vaccine to trigger an immune response in the following groups (the numbers given are for those who received Pandemrix in the studies):

- healthy adults aged between 18 and 60 years (180 subjects in two studies);
- healthy elderly subjects over the age of 60 years (120 subjects in one study);
- healthy children (210 aged between three and 17 years, and 50 aged between six and 35 months, in three studies).

The studies in children also allowed the effectiveness of Pandemrix as a 0.5 ml dose to be compared with that of a 0.25 ml dose.

What benefit has Pandemrix shown during the studies?

In all of the studies, 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.

The CHMP noted that a single dose was able to trigger immunity to a satisfactory level in adults (including the elderly), adolescents and children from 10 years of age. In children aged between six months and nine years, 0.25 ml doses were as effective as 0.5 ml doses.

What is the risk associated with Pandemrix?

The most common side effects with Pandemrix in adults (seen with more than 1 in 10 doses of the vaccine) are headache, arthralgia (joint pain), myalgia (muscle pain), swelling and pain at the site of the injection, shivering, increased sweating and fatigue (tiredness). Side effects are similar in children. For the full list of all side effects reported with Pandemrix, see the package leaflet.

Pandemrix 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 egg or chicken protein, ovalbumin (a protein in egg white), formaldehyde, gentamicin sulphate (an antibiotic) and sodium deoxycholate. Vaccination should be postponed in subjects with severe fever or an acute (short-lived) infection.

Why has Pandemrix been approved?

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

Pandemrix was originally authorised under 'exceptional circumstances', because, for scientific reasons, limited information was available at the time of approval. As the company had supplied the additional information requested, the 'exceptional circumstances' ended on 12 August 2010.

Following rare cases of narcolepsy (a rare sleep disorder that causes a person to fall asleep suddenly and unexpectedly) among people given the vaccine, it was concluded that Pandemrix should only be used if the recommended seasonal influenza vaccine is not available and if immunisation against H1N1 is still needed.

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

A risk management plan has been developed to ensure that Pandemrix 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 Pandemrix, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Pandemrix

The European Commission granted a marketing authorisation valid throughout the European Union for Pandemrix on 20 May 2008.

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

This summary was last updated in 05-2016.