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EPAR summary for the public

Vepacel

Influenza vaccine (whole virion, inactivated)

This is a summary of the European public assessment report (EPAR) for Vepacel. 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 Vepacel.

What is Vepacel?

Vepacel is a vaccine. It contains influenza (flu) viruses that have been inactivated (killed). Vepacel contains a flu strain called A/Vietnam/1203/2004 (H5N1).

What is Vepacel used for?

Vepacel is a vaccine for use in adults and children from 6 months of age to protect against flu caused by the H5N1 ("bird flu") subtype of the influenza A virus. The vaccine is given according to official recommendations.

The vaccine can only be obtained with a prescription.

How is Vepacel used?

The vaccine is given by injection into the shoulder or thigh in two single doses, at least three weeks apart.

How does Vepacel work?

Vepacel is a 'prepandemic' vaccine. This is a type of vaccine to be used to protect against a new strain of flu that may cause a future influenza pandemic. The vaccine has been developed so that it can be used before or during a flu pandemic to provide protection against the H5N1 virus. A flu pandemic happens when a new strain of flu virus appears that can spread easily from person to person because

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people have no immunity (protection) against it. A pandemic can affect most countries and regions around the world. Health experts are concerned that a future flu pandemic could be caused by a strain of the H5N1 virus.

Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. This vaccine contains a strain of the H5N1 virus. 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 parts as 'foreign' and makes antibodies against them. The immune system will then be able to produce antibodies more quickly when it is exposed to the virus again. This may help to protect against the disease caused by the virus.

The viruses used in Vepacel are grown in mammal cells ('vero cells'), as opposed to hen's eggs.

How has Vepacel been studied?

Two main studies provided data on vaccination with Vepacel in adults. Both studies looked separately at people aged above and below 60 years old. The first main study involved 563 healthy adults, while the second study involved around 3,600 adults including those at higher risk of flu (such as people with a long-term illness or a weakened immune system). In both studies, participants were given two doses of Vepacel followed by a booster dose (given after six months, one year or two years) of a vaccine containing different strengths of the same H5N1 flu strain as in Vepacel or a different H5N1 flu strain.

Vepacel has also been studied in a main study involving 657 healthy children aged 6 months to 17 years, who were given two doses of Vepacel, three weeks apart. Some children also received a booster dose of a vaccine containing a different H5N1 flu strain after one year.

All of the studies looked at the ability of the vaccine to trigger the production of antibodies ('immunogenicity') against H5N1.

What benefit has Vepacel shown during the studies?

According to criteria laid down by the CHMP, a prepandemic vaccine needs to bring about protective levels of antibodies in at least 70% of adults for it to be considered suitable.

Vaccination with Vepacel in adults produced an antibody response that met these criteria. In the first main study, at 21 days after the second injection, 72.5% of adults under 60 and 74.1% of adults aged 60 and over had levels of antibodies that would protect them against H5N1. In the second main study, 85.8% of healthy adults under 60 and 80.2% of healthy adults aged 60 and over had protective levels of antibodies. Moreover, protective levels of antibodies were seen in 71.6% of patients with a weakened immune system and 77.5% of patients with a long-term illness. In both studies, patients who received Vepacel and a booster with a different H5N1 flu strain produced antibodies that could react with several strains of H5N1 virus. This may help to provide protection in the event of a pandemic caused by a new strain of the H5N1 virus.

The study in children showed that vaccination with Vepacel brought about similar levels of antibodies to those seen in adults: at 21 days after the second injection, 85.4% of children aged 9 to 17 years, 72.9% of children aged 3 to 8 years and 68.8% of children aged 6 to 35 months had levels of antibodies that would protect them against H5N1. The booster vaccination (one year after the 2-dose vaccination with Vepacel) also produced a strong antibody response against the strains used in the booster and in Vepacel.

What is the risk associated with Vepacel?

The most common side effects with Vepacel (seen in more than 1 person in 10) in adults are headache, fatigue (tiredness) and pain at the site of injection. Side effects are similar in children. For the full list of all side effects reported with Vepacel, see the package leaflet.

Vepacel 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, sucrose, trypsin or vero cell protein. If vaccination is necessary, facilities to resuscitate patients need to be immediately available.

Why has Vepacel been approved?

The CHMP decided that the benefits of Vepacel are greater than its risks and recommended that it be granted a marketing authorisation. The Committee noted that Vepacel produced a good antibody response in healthy adults and an acceptable response in healthy adults aged 60 and over and in patients with a weakened immune system or long-term illness. The Committee also noted that Vepacel produced a reasonable antibody response against other H5N1 strains that could potentially cause a flu pandemic. No major safety issues were seen during the studies and the side effects seen were generally mild and similar to those seen with other flu vaccines.

The use of Vepacel was later extended to children from 6 months of age since the vaccine was shown to produce a good antibody response also in this population, with a safety profile similar to that seen in adults.

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

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

Other information about Vepacel

The European Commission granted a marketing authorisation valid throughout the European Union for Vepacel on 17 February 2012.

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

This summary was last updated in 11-2013.