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EPAR summary for the public

Optaflu

influenza vaccine (surface antigen, inactivated, prepared in cell cultures)

This is a summary of the European public assessment report (EPAR) for Optaflu. It explains how the Committee for Medicinal Products for Human Use (CHMP) assesser the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Optaflu.

What is Optaflu?

Optaflu is a vaccine, which is available as a suspension for injection in a pre-filled syringe. The vaccine contains 'surface antigens' from three different strains (types) of influenza (flu) virus: A/California/7/2009 (H1N1)pdm09-like strain; ^/Switzerland/9715293/2013 (H3N2)–like strain; and B/Phuket/3073/2013-like strain.

What is Optaflu used for?

Optaflu is used to vaccinate clubs against flu, especially those who are at an increased risk of developing complications from the disease. The use of the vaccine should be based on official recommendations.

The vaccine can or ly to obtained with a prescription.

How is Optailu used?

Optaf'a 's given as one injection of 0.5 ml into the muscle at the top of the arm.

How does Optaflu work?

Optaflu is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Optaflu contains fragments from the surface of three different strains of flu virus. When a person is given the vaccine, the immune system recognises the virus fragments as 'foreign' and makes antibodies against them. In the future, the immune system will be

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able to produce antibodies more quickly when it is exposed to any of these virus strains. The antibodies will then help to protect against the disease caused by these strains of the flu virus.

Each year, the World Health Organization (WHO) makes recommendations on which flu strains should be included in vaccines for the upcoming flu season. Optaflu contains fragments (surface antigens) of the virus strains that are expected to cause flu in the upcoming season, according to the recommendations from the WHO for the northern hemisphere and from the European Union (EU), need to be included in Optaflu before the vaccine can be used.

The viruses used to obtain the surface antigen that are included in Optaflu are grown in mammalian cells, unlike those used for other flu vaccines, which are grown in hen's eggs.

How has Optaflu been studied?

The ability of Optaflu to trigger the production of antibodies (immunogenicity) was firs as essed using a formulation of the vaccine that included the virus strains expected to cause flu in the 2004/2005 season. The vaccine's effectiveness was assessed in one main study involving 2 c54 adults, around half of whom were elderly (over 60 years of age). The effects of Optaflu were conspared to those of a similar flu vaccine that was made in eggs. The study compared the ability of the two vaccines to trigger the production of antibodies (immunogenicity), by comparing an body levels before injection and three weeks afterwards.

The immunogenicity and safety of subsequent formulations of the vaccine have also been examined in studies.

What benefit has Optaflu shown during the studies?

In the original main study, both Optaflu and the comparator vaccine brought about adequate levels of antibodies for protection against all three flu strains, as defined in criteria laid down by the CHMP for flu vaccines. The two vaccines were similar in triggering the production of antibodies, both in adults 60 years of age and below, and in the elderny

Later seasonal formulations of Opt flu have been shown to bring about similar antibody responses against the three flu strains included in the vaccine to those seen in the main study.

What is the risk as sociated with Optaflu?

The most common an 'e offects with Optaflu (seen in more than 1 patient in 10) are headache, reddening of the skin muscle pain, pain at the site of injection, malaise (feeling unwell) and fatigue (tiredness). There side effects usually disappear within one to two days without treatment. For the full list of all side onects reported with Optaflu, see the package leaflet.

People who have a fever or an acute (short-lived) infection should not receive the vaccine until they have recovered. For the full list of restrictions, see the package leaflet.

Why has Optaflu been approved?

The CHMP decided that Optaflu's benefits 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 **Optaflu?**

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

Other information about Optaflu

The European Commission granted a marketing authorisation valid throughout the European Unicert Optaflu on 1 June 2007.

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