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EPAR summary for the public

Fluenz

influenza vaccine (live attenuated, nasal)

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

What is Fluenz?

Fluenz is a vaccine which is available as a nasal spray to protect against influenza A (sub-types H1N1 and H3N2) and influenza B.

It contains three live attenuated (weakened) influenza (flu) virus strains: A/California/7/2009 (H1N1)pdm09-like strain; A/Victoria/361/2011 (H3N2)-like strain; and B/Massachusetts/2/2012-like strain.

What is Fluenz used for?

Fluenz is used to prevent flu in children and adolescents from 24 months to less than 18 years old.

The vaccine can only be obtained with a prescription. Its use should be based on official recommendations.

How is Fluenz used?

Fluenz is given as a nasal spray using a single-use nasal applicator (0.1 ml sprayed into each nostril). It must only be used as a nasal spray and must not be injected. Children who have not been previously vaccinated against seasonal flu should be given a second dose after at least four weeks.



How does Fluenz work?

Fluenz is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Fluenz contains strains of flu virus that have first been weakened so that they do not cause disease.

When a person is given the vaccine, the immune system recognises the virus as 'foreign' and makes defences against it. The immune system will then be able to respond more quickly when it is exposed to the virus again. This will help to protect against the disease caused by the virus.

Each year, the World Health Organization (WHO) makes recommendations on which flu strains should be included in vaccines for the upcoming flu season. These virus strains need to be included in Fluenz before it can be used. Fluenz will be updated with weakened virus strains type A-H1N1, type A-H3N2 and type B for each season, according to recommendations for the northern hemisphere from the WHO and from the European Union.

The viruses used in Fluenz are grown in hens' eggs.

How has Fluenz been studied?

Nine main studies involving around 24,000 children and adolescents and four studies involving around 11,000 adults compared Fluenz with either placebo (a dummy vaccine) or another injectable flu vaccine containing inactivated (killed) viral material from the same three flu strains. The flu strains were selected according to the influenza season. The main measure of effectiveness was the number of laboratory-confirmed cases of flu caused by the three strains during the given flu season, although one of the studies in adults measured the number of cases of feverish illness (as opposed to confirmed flu cases).

What benefit has Fluenz shown during the studies?

In the studies in children and adolescents, Fluenz reduced the number of flu cases caused by the three flu strains by between 62% and 100% compared with placebo and by between 35% and 53% compared with the comparator inactivated vaccine.

The studies in adults showed that Fluenz may have some benefits compared with placebo but the results were inconsistent. Some studies also suggested that Fluenz was not as effective as the comparator inactivated vaccine in adults.

What is the risk associated with Fluenz?

The most common side effects with Fluenz (seen in more than 1 patient in 10) are reduced appetite, headache, blocked or runny nose and malaise (feeling unwell). For the full list of all side effects reported with Fluenz, see the package leaflet.

Fluenz must not be used in people who are hypersensitive (allergic) to the active substances or any of the other ingredients, to gentamicin (a type of antibiotic), or to eggs or egg proteins. It must also not be given to people with weakened immune systems due to conditions such as blood disorders, symptomatic HIV infection and cancer or as a result of certain medical treatments. It must also not be given to children who are receiving treatment with salicylates (painkillers such as aspirin).

Why has Fluenz been approved?

The CHMP noted that the studies showed convincingly that Fluenz was more effective than placebo and the comparator inactivated vaccine in children and adolescents, but not in adults. The CHMP therefore decided that Fluenz's benefits are greater than its risks in children and adolescents from 24 months to less than 18 years old and recommended that it be given marketing authorisation in this patient group.

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

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

Other information about Fluenz

The European Commission granted a marketing authorisation valid throughout the European Union for Fluenz on 27 January 2011.

The full EPAR for Fluenz can be found on the Agency's website [ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports](http://ema.europa.eu/Find%20medicine/Human%20medicines/European%20Public%20Assessment%20Reports). For more information about treatment with Fluenz, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 01-2014.