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Fluenz (*influenza vaccine (live attenuated, nasal)*)

An overview of Fluenz and why it is authorised in the EU

What is Fluenz and what is it used for?

Fluenz is a vaccine used to help protect children and adolescents from 2 years to less than 18 years old against seasonal influenza (flu).

Seasonal influenza epidemics are mainly caused by two types of influenza virus, known as influenza A and B. Each of these circulate as different subtypes or lineages, which change over time. Fluenz contains live attenuated (weakened) types of the influenza virus; two type A viruses (subtypes A-H1N1 and A-H3N2) and one type B virus (Victoria lineage), which are selected in accordance with the official recommendation for the annual flu season.

How is Fluenz used?

Fluenz can only be obtained with a prescription and should be used in accordance with official recommendations issued at national level by public health bodies.

Fluenz is available as a nasal spray. The recommended dose is one nasal spray in each nostril. Children who have not been previously vaccinated against seasonal influenza should receive a second dose at least 4 weeks after the first.

For more information about using Fluenz, see the package leaflet or contact your doctor or pharmacist.

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 flu virus strains that are grown in hens' eggs. These have first been weakened so that they do not cause disease. When a person is given the vaccine, the immune system recognises the weakened virus strains 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.

Each year, the World Health Organization (WHO) makes recommendations on which flu strains should be included in vaccines for the upcoming flu season in the northern hemisphere; the virus strains in Fluenz are updated for each season based on this official recommendation. This helps to protect against the disease caused by the virus for the upcoming flu season.

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What benefits of Fluenz have been shown in studies?

Five main studies involving around 18,000 children up to 6 years of age compared Fluenz with either placebo (a dummy treatment) or an injectable flu vaccine containing inactivated (killed) viral material from comparable flu strains. The flu strains were selected each year in accordance with the recommendation for the corresponding influenza season.

Four studies showed that, compared with placebo, two doses of Fluenz reduced the number of flu cases caused by the three strains in Fluenz by between 73% and 93%. Protection against flu caused by any strain (including strains not included in the vaccine) was between 70% and 86%.

In the main study comparing Fluenz with an injected flu vaccine containing comparable virus strains, Fluenz reduced the number of flu cases caused by the three flu strains in Fluenz by around 45% and against any strain by 55%. A supportive study showed that protection in children and adolescents aged 6 to 17 years was comparable between Fluenz and an injected flu vaccine.

What are the risks associated with Fluenz?

For the full list of side effects and restrictions with Fluenz, see the package leaflet. The most common side effects with Fluenz (which may affect more than 1 in 10 children) include a blocked or runny nose, decreased appetite, headache and feeling unwell.

Fluenz must not be used in children 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 children with a weakened immune system due to conditions such as blood disorders, symptomatic HIV infection, cancer or certain medical treatments, nor to children who are receiving treatment with salicylates (painkillers such as aspirin).

Why is Fluenz authorised in the EU?

Fluenz is given as a spray into each nostril, providing a needle-free option for children and adolescents. Studies showed that Fluenz was more effective than placebo at protecting children and adolescents from circulating flu strains. The safety of the nasal spray is expected to be acceptable. The European Medicines Agency therefore decided that Fluenz's benefits are greater than its risks and that it can be authorised for use in the EU.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Fluenz have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Fluenz are continuously monitored. Suspected side effects reported with Fluenz are carefully evaluated and any necessary action taken to protect patients.

Other information about Fluenz

Fluenz received a marketing authorisation valid throughout the EU on 3 June 2024.

Further information on Fluenz can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/Fluenz-0.

This overview was last updated in 06-2024.