

Package leaflet: Information for the user

Fluenz® nasal spray suspension Influenza vaccine (live attenuated, nasal)

Read all of this leaflet carefully before the vaccine is given because it contains important information for you or your child.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- This vaccine has been prescribed for you or your child only. Do not pass it on to others.
- If any of the side effects gets serious, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Fluenz is and what it is used for
2. What you need to know before you are given Fluenz
3. How Fluenz is given
4. Possible side effects
5. How to store Fluenz
6. Contents of the pack and other information

1. What Fluenz is and what it is used for

Fluenz is a vaccine to prevent influenza (flu). It is used in children and adolescents 24 months to less than 18 years of age. Fluenz will help to protect against the virus strains contained in the vaccine, and other strains closely related to them.

How Fluenz works

When a person is given the vaccine, the immune system (the body's natural defence system) will produce its own protection against the influenza virus. None of the ingredients in the vaccine can cause the flu.

Fluenz vaccine viruses are grown in chicken eggs. Each year the vaccine targets three strains of influenza, following the annual recommendations by the World Health Organisation.

2. What you need to know before you are given Fluenz

You will not be given Fluenz:

- **if you are allergic** to gentamicin, gelatin or any of the other ingredients of this vaccine (listed in section 6 "Contents of the pack and other information").
- if you have ever had a severe allergic reaction to eggs or egg proteins. For signs of allergic reactions, see section 4 "Possible side effects".
- if you have a **blood disorder** or a **cancer that affects the immune system**.
- if you have been **told by your doctor** that you have a **weakened immune system** as a result of a disease, medicine or other treatment.
- **if you are already taking acetylsalicylic acid** (a substance present in many medicines used to relieve pain and lower fever). This is because of the risk of a very rare but serious disease (*Reye's syndrome*).

If any of these apply, **tell your doctor, nurse or pharmacist.**

Warnings and precautions

Talk to your doctor, nurse or pharmacist before vaccination:

- if the **child is less than 24 months of age**. Children less than 24 months of age should not receive this vaccine because of the risk of side effects.
- if you have **severe asthma** or are currently wheezing.
- if you are in **close contact with someone with a severely weakened immune system** (for example, a bone marrow transplant patient needing isolation).

If any of these apply, **tell your doctor, nurse or pharmacist before vaccination**. He or she will decide if Fluenz is suitable for you.

Other medicines, other vaccines and Fluenz

Tell your doctor, nurse or pharmacist if the person being vaccinated is taking, has recently taken or might take any other medicines, including medicines that do not require a prescription.

- **Do not give *acetylsalicylic acid*** (a substance present in many medicines used to relieve pain and lower fever) **to children** for 4 weeks after vaccination with Fluenz unless your doctor, nurse or pharmacist tells you otherwise. This is because of the risk of Reye's syndrome, a very rare but serious disease that can affect the brain and liver.
- **It is recommended that Fluenz is not given** at the same time as influenza-specific **antiviral medicines**, such as *oseltamivir* and *zanamivir*. This is because the vaccine may work less effectively.

Your doctor, nurse or pharmacist will decide if Fluenz can be given at the same time as other vaccines.

Pregnancy and breast-feeding

- If you are **pregnant**, think you may be pregnant, plan to become pregnant soon or are breast-feeding, **tell your doctor, nurse or pharmacist** before receiving this vaccine. Fluenz is **not recommended** for women who are pregnant or are breast-feeding.

Driving and using machines

- Fluenz has no or negligible influence on the ability to drive and use machines.

3. How Fluenz is given

Fluenz will be administered under the supervision of a doctor, nurse or pharmacist.

Fluenz must only be used as a nasal spray.

Fluenz must not be injected.

Fluenz will be given as a spray in each nostril. You can breathe normally while you are given Fluenz. You do not need to actively inhale or sniff.

Dosage

The recommended dose for children and adolescents is 0.2 ml Fluenz, administered as 0.1 ml in each nostril. **Children who have not previously had an influenza vaccine** will receive a second, follow-up dose after an interval of at least 4 weeks. Follow your doctor, nurse or pharmacist's instructions about if and when your child should return for the second dose.

If you have any further questions on this vaccine, ask your doctor, nurse or pharmacist.

4. Possible side effects

Like all medicines, this vaccine can cause side effects, although not everybody gets them. In clinical studies with the vaccine, most side effects were mild in nature and short term.

Ask your doctor, nurse or pharmacist if you want more information about possible side effects from Fluenz.

Some side effects may be serious

Very rare

(may affect up to 1 in 10,000 people):

- severe allergic reaction: signs of a severe allergic reaction may include shortness of breath and swelling of the face or tongue.

Tell your doctor straight away or seek urgent medical care if you experience any of the effects above.

Other possible side effects of Fluenz

Very common

(may affect more than 1 in 10 people):

- runny or stuffy nose
- reduced appetite
- weakness

Common

(may affect up to 1 in 10 people):

- fever
- muscle aches
- headache

Uncommon

(may affect up to 1 in 100 people):

- rash
- nose bleed
- allergic reactions

Reporting of side effects

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fluenz

Keep this vaccine out of the sight and reach of children.

Do not use this vaccine after the expiry date which is stated on the applicator label after the letters EXP.

Store in a refrigerator (2°C to 8°C). Do not freeze.

Keep the nasal applicator in the outer carton in order to protect from light.

Before use, the vaccine may be taken out of the refrigerator once for a maximum period of 12 hours at a temperature not above 25°C. If the vaccine has not been used after this 12 hour period, it should be discarded.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Fluenz contains

The active substances are:

Reassortant influenza virus* (live attenuated) of the following strains**:

A/Victoria/4897/2022 (H1N1)pdm09 - like strain (A/Norway/31694/2022, MEDI 369815)	10 ^{7.0±0.5} FFU***
A/Thailand/8/2022 (H3N2) - like strain (A/Thailand/8/2022, MEDI 370626)	10 ^{7.0±0.5} FFU***
B/Austria/1359417/2021 - like strain (B/Austria/1359417/2021, MEDI 355292)	10 ^{7.0±0.5} FFU***
.....per 0.2 ml dose	

* propagated in fertilised hens' eggs from healthy chicken flocks.

** produced in VERO cells by reverse genetic technology. This product contains genetically modified organisms (GMOs).

*** Fluorescent Focus Units.

This vaccine complies with the WHO (World Health Organisation) recommendations (Northern Hemisphere) and EU decision for the 2024/2025 season.

The other ingredients are sucrose, dipotassium phosphate, potassium dihydrogen phosphate, gelatin (porcine, Type A), arginine hydrochloride, monosodium glutamate monohydrate and water for injections.

What Fluenz looks like and contents of the pack

This vaccine is presented as a nasal spray suspension in a single-use nasal applicator (0.2 ml) in a pack size of 1 and 10. Not all pack sizes may be available.

The suspension is colourless to pale yellow, clear to slightly cloudy. Small white particles may be present.

Marketing Authorisation Holder

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Other sources of information

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

Product name

Fluenz nasal spray suspension

Reference number

17901/0378

This is a service provided by the Royal National Institute of the Blind.