

Package leaflet: Information for the user

Fluenz® nasal spray suspension Influenza vaccine (live, 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 you get any side effects, 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 2 years 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 the active ingredients, gentamicin (trace residue from the manufacturing process), or any of the other ingredients of this vaccine listed in section 6.
- if you have ever had a severe allergic reaction to eggs or egg proteins. For signs of allergic reactions, see section 4.
- 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 (such as acute and chronic leukaemias, lymphoma, symptomatic HIV infection, cellular immune deficiencies, and high-dose corticosteroids).
- **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

Your doctor or nurse will make sure that appropriate medical treatment and supervision is readily available in case of a rare anaphylactic reaction (a very severe allergic reaction with symptoms such as difficulty in breathing, dizziness, a weak and rapid pulse and skin rash) following the administration.

Talk to your doctor, nurse or pharmacist before vaccination:

- if you have **severe asthma** or are currently wheezing.
- If you have severe acute illness associated with fever or infection, or if you have nasal blockage. Your doctor may decide to delay your vaccination until your fever or nasal blockage is gone.
- if you are in **close contact with someone with a severely weakened immune system** (for example, a bone marrow transplant patient needing isolation).
- if you have any birth defects that affect the bones and tissues of the skull and face, which have not undergone surgical correction.

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

Children less than 2 years of age

Children less than 2 years of age should not receive this vaccine because of the risk of side effects.

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 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.

Dose

The recommended dose for children and adolescents is 0.2 ml Fluenz, administered as 0.1 ml in each nostril. **Children 2 to 8 years of age 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.

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
- feeling generally unwell

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 and the carton after the letters EXP.

Store in a refrigerator (2°C - 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 three strains**:

| | |
|--|--------------------------|
| A/Victoria/4897/2022 (H1N1)pdm09 - like strain (A/Norway/31694/2022, MEDI 369815) | $10^{7.0\pm 0.5}$ FFU*** |
| A/Croatia/10136RV/2023 (H3N2) - like strain (A/Perth/722/2024, MEDI 392611) | $10^{7.0\pm 0.5}$ FFU*** |
| B/Austria/1359417/2021 - like strain (B/Austria/1359417/2021, MEDI 355292) | $10^{7.0\pm 0.5}$ 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 2025/2026 season.

The vaccine may contain traces of the following substances: egg proteins (e.g. ovalbumin) and gentamicin. The other ingredients are sucrose, dipotassium phosphate, potassium dihydrogen phosphate, gelatin, 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 (0.2ml) in a single-use nasal applicator (Type 1 glass). Pack size of 1 and 10 nasal applicators. 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

AstraZeneca UK Limited,

1 Francis Crick Avenue,
Cambridge,
CB2 0AA,
UK.

Manufacturer

MedImmune UK Limited,
Plot 6, Renaissance Way,
Boulevard Industry Park,
Speke,
Liverpool, L24 9JW,
United Kingdom

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INF 25 0007

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 | Reference number |
|-------------------------------|-------------------------|
| Fluenz nasal spray suspension | 17901/0378 |

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

Instructions for healthcare professionals

The following information is intended for healthcare professionals only:

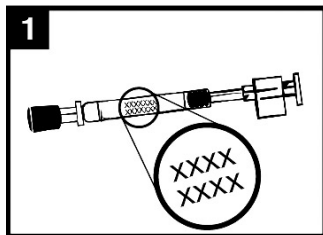
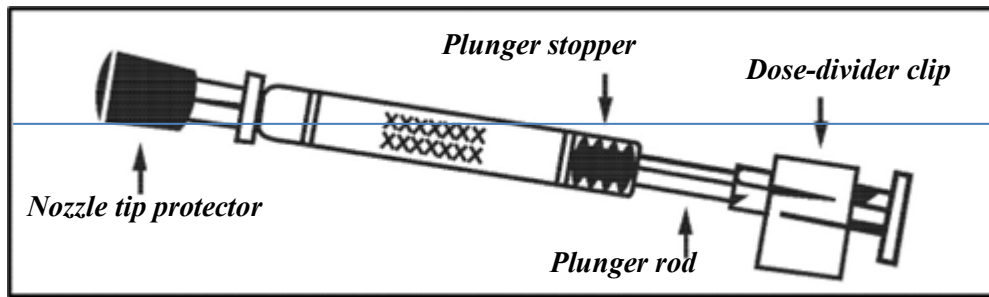
Fluenz is for single nasal use only.

- **Do not use with a needle.** Do not inject.

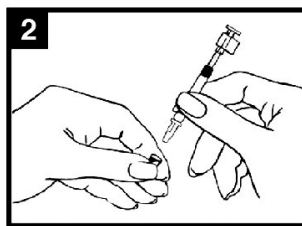


- Do not use Fluenz if the expiry date has passed or the sprayer appears damaged, for example, if the plunger is loose or displaced from the nasal applicator or if there are any signs of leakage.
- Check the appearance of the vaccine before administration. The suspension should be colourless to pale yellow, clear to opalescent. Small white particles may be present.
- Fluenz is administered as a divided dose in both nostrils as described below (see section 3).
- After administering half of the dose in one nostril, administer the other half of the dose in the other nostril immediately or shortly thereafter.

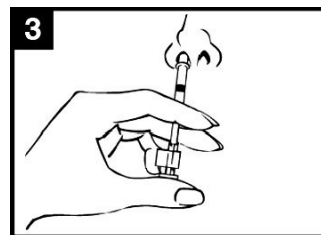
- The patient can breathe normally while the vaccine is being administered – there is no need to actively inhale or sniff.



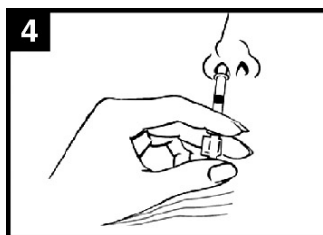
1
Check expiry date
 Product must not be used after date on applicator label.



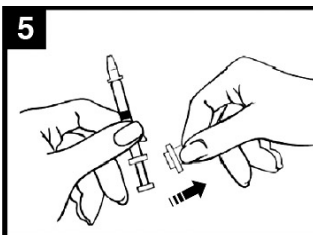
2
Prepare the applicator
 Remove nozzle tip protector. Do not remove dose-divider clip at the other end of the applicator.



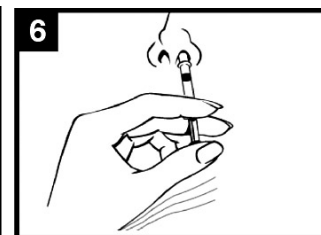
3
Position the applicator
 With the patient in an upright position, place the tip just inside the nostril to ensure Fluenz is delivered into the nose.



4
Depress the plunger
 With a single motion, depress plunger as rapidly as possible until the dose-divider clip prevents you from going further.



5
Remove dose-divider clip
 For administration in the other nostril, pinch and remove the dose-divider clip from plunger.



6
Spray in other nostril
 Place the tip just inside the other nostril and with a single motion, depress plunger as rapidly as possible to deliver remaining vaccine.

See section 5 for advice on storage and disposal.