**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.

**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.

**3. 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. 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) 107.0±0.5 FFU\*\*\*

A/Croatia/10136RV/2023 (H3N2) - like strain

(A/Perth/722/2024, MEDI 392611) 107.0±0.5 FFU\*\*\*

B/Austria/1359417/2021 - like strain

(B/Austria/1359417/2021, MEDI 355292) 107.0±0.5 FFU\*\*\*

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\* 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.