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.

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.

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. The vaccine targets three strains of influenza virus each year, 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 eggs, egg proteins, gentamicin, or gelatin or any of the other ingredients of Fluenz (listed in section 6 "Contents of the pack and other information"). 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 under 18 years** of age and **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.

- **Do not give acetylsalicylic acid to children aged less than 18 years** 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**. 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.

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 when your child should return for the second dose.

4. Possible side effects

Like all medicines, Fluenz 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 1,000,000 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
- headache

Common
(may affect up to 1 in 10 people):
- fever
- muscle aches

Uncommon
(may affect up to 1 in 100 people):
- rash
- nose bleed
- allergic reactions

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.

5. How to store Fluenz

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

Do not use Fluenz 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.

Protect from light.

Before use, the vaccine may be taken out of the refrigerator, without being replaced, 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 disposed of.

Any unused product or waste material should be disposed of in accordance with local requirements for medical waste. 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/California/7/2009 (H1N1)pdm09-like strain
(A/California/7/2009, MEDI 228029) $10^{7.0\pm0.5}$ FFU***

A/Victoria/361/2011 (H3N2)-like strain
(A/Texas/50/2012, MEDI 237514) $10^{7.0\pm0.5}$ FFU***

B/Massachusetts/2/2012-like strain
(B/Massachusetts/2/2012, MEDI 237751) $10^{7.0\pm0.5}$ 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 2013/2014 season.

The other ingredients are sucrose, dibasic potassium phosphate, monobasic potassium 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 10.

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

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: MedImmune, LLC, Lagelandseweg 78, 6545 CG Nijmegen, Netherlands, (Tel) +31 24 371 7310

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

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This leaflet was last revised in 08/2013.

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

Fluenz is a trademark of MedImmune, LLC.

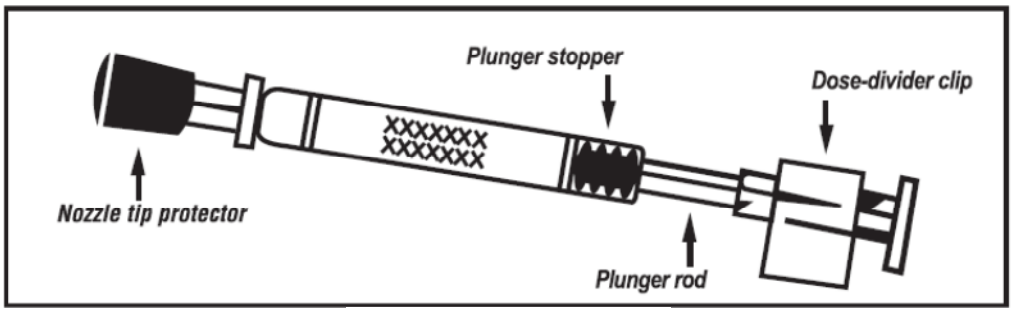
Instructions for health professionals

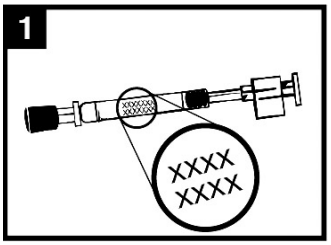
The following information is intended for medical or healthcare professionals only:

Fluenz is for nasal use only.

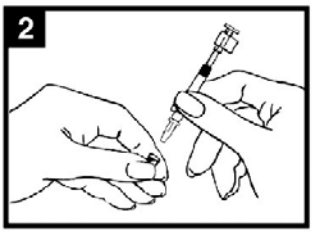
- **Do not use with a needle.** Do not inject.

- Fluenz is administered as a divided dose in both nostrils as described below. (See also, *How Fluenz is given,* in 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.

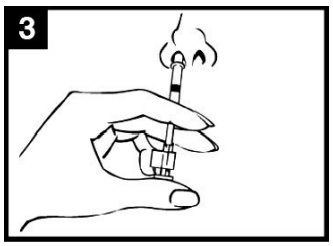




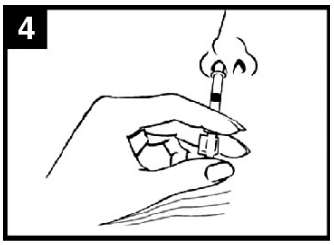
Check expiry date
Product must be used before date on applicator label.



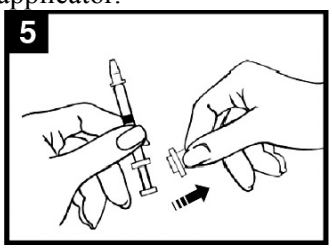
Prepare the applicator
Remove rubber tip protector. Do not remove dose-divider clip at the other end of the applicator.



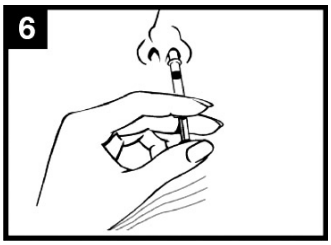
Position the applicator
With the patient in an upright position, place the tip just inside the nostril to ensure Fluenz is delivered into the nose.



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



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



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.