

Package leaflet: Information for the user

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

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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

1. What Fluenz Tetra is and what it is used for

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

How Fluenz Tetra works

Fluenz Tetra is identical to Fluenz (a nasal influenza vaccine containing three strains), except Fluenz Tetra provides protection against an additional influenza strain.

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

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

You will not be given Fluenz Tetra:

- **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 Tetra is suitable for you.

Other medicines, other vaccines and Fluenz Tetra

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 Tetra 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 Tetra 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 Tetra 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 Tetra is **not recommended** for women who are pregnant or are breast-feeding.

Driving and using machines

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

3. How Fluenz Tetra is given

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

Fluenz Tetra must only be used as a nasal spray.

Fluenz Tetra must not be injected.

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

Dosage

The recommended dose for children and adolescents is 0.2 ml Fluenz Tetra, 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 Tetra.

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 Tetra

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

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 Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fluenz Tetra

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 Tetra contains

The active substances are:

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

A/California/7/2009 (H1N1)pdm09 - like strain (A/Bolivia/559/2013, MEDI 255962)	10 ^{7.0±0.5} FFU***
A/Hong Kong/4801/2014 (H3N2) - like strain (A/New Caledonia/71/2014, MEDI 263122)	10 ^{7.0±0.5} FFU***
B/Brisbane/60/2008 - like strain (B/Brisbane/60/2008, MEDI 228030)	10 ^{7.0±0.5} FFU***
B/Phuket/3073/2013 - like strain (B/Phuket/3073/2013, MEDI 254977)	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 recommendations (World Health Organisation) and EU decision for the 2016/2017 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 Tetra 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 in your country.

The suspension is colourless to pale yellow, 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 15th December 2016.

Other sources of information

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

Instructions for healthcare professionals

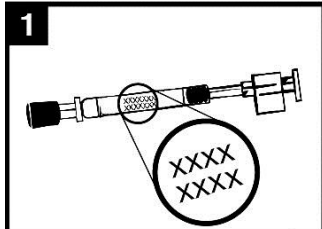
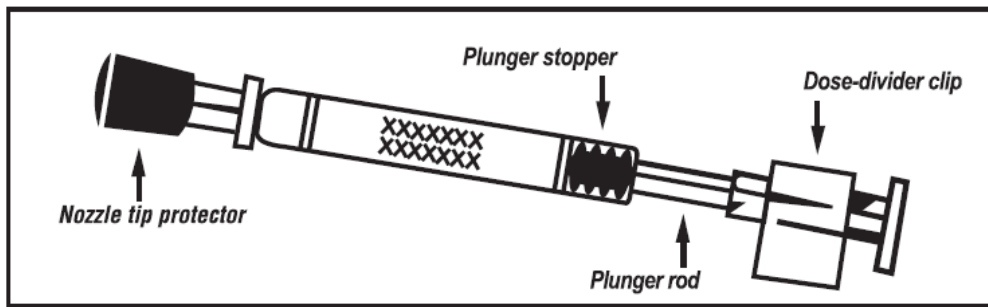
The following information is intended for healthcare professionals only:

Fluenz Tetra is for nasal use only.

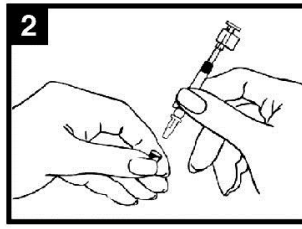
- **Do not use with a needle.** Do not inject.



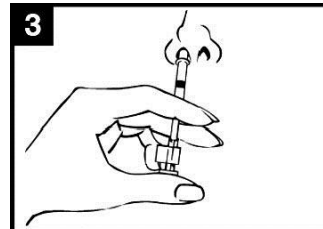
- Do not use Fluenz Tetra if the expiry date has passed or the sprayer appears damaged, for example, if the plunger is loose or displaced from the sprayer or if there are any signs of leakage.
- Fluenz Tetra is administered as a divided dose in both nostrils as described below. (See also, *How Fluenz Tetra 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.



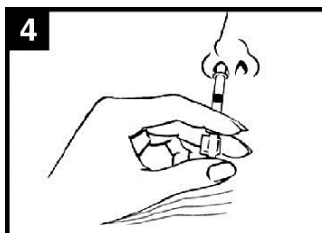
1
Check expiry date
 Product must be used before date on applicator label.



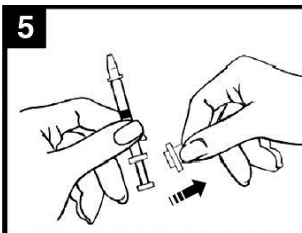
2
Prepare the applicator
 Remove rubber tip protector. Do not remove dose-divider clip at the other end of the applicator.



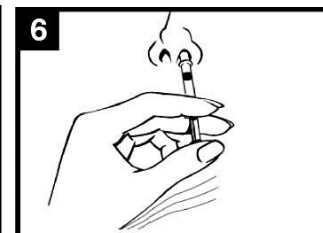
3
Position the applicator
 With the patient in an upright position, place the tip just inside the nostril to ensure Fluenz Tetra is delivered into the nose.



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.