

Flu Immunisation

6. Contents of the pack and other information

What FluZn Tetra contains

The active substances are: Reassortant influenza virus* (live attenuated) of the following four strains**:

A/Brisbane/02/2018 (H1N1)pdm09 - like strain
 (A/Switzerland/3330/2017, MEDI 307134) 107.0±0.5 FFU***

A/Kansas/14/2017 (H3N2) - like strain
 (A/Kansas/14/2017, MEDI 308763) 107.0±0.5 FFU***

B/Colorado/06/2017 - like strain
 (B/Colorado/06/2017, MEDI 293454) 107.0±0.5 FFU***

B/Phuket/3073/2013 - like strain
 (B/Phuket/3073/2013, MEDI 254977) 107.0±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 2019/2020 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 FluZn 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: AstraZeneca AB, SE-151 85 Södertälje, Sweden
 Manufacturer: MedImmune, UK Limited, Plot 6, Renaissance Way, Boulevard Industry Park, Speke, Liverpool, L24 9JW, United Kingdom

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

United Kingdom: AstraZeneca UK Ltd Tel: +44 1582 836 836

This leaflet was last revised in 08/2019.
 INF 19 0012

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

School Health Immunisation Team
 Halton 0-19 Service
 The Health Care Resource Centre
 Oaks place
 Caldwell Road
 Widnes
 WA8 7GD

Tel: 0151 495 5066

Email: bchft.haltonimmteam@nhs.net

Web: www.bridgewater.nhs.uk

Date 21/10/19.

To the parents/carers of:-

DOB:-

Today your child has received their vaccination against Flu.

Children may commonly develop a runny or blocked nose, headache, general tiredness and some loss of appetite. These minor side effects may last no longer than a few days.

Attached is the Patient Information Leaflet which accompanies the vaccine.

If your child has a health condition that puts them at a greater risk of the effects of flu (including serious breathing problems, serious heart conditions, severe kidney or liver disease, diabetes, problems with the spleen, immunosuppression and a condition that affects the nervous system such as cerebral palsy) they may be invited to have a flu vaccination by your GP surgery in the coming weeks. If your child gets invited for a flu vaccination by your child's GP surgery, please inform them that your child has already received their 2019 flu vaccination.

Please note – If your child has a health condition that puts them at greater risk of the effects of flu and this is your child's first ever flu vaccination a 2nd dose of flu vaccination is recommended in 4 weeks. Please make an appointment for your child to receive the 2nd dose at your child's GP surgery in 4 weeks, taking this letter with you.

For more advice or information please visit www.nhs.uk or

contact your School-aged Immunisation Team on 0151 495 5066

Package leaflet: information for the user

Fluenz Tetra 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 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

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 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 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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store Fluenz Tetra

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