The content of this leaflet is for
UK Healthcare Professionals only

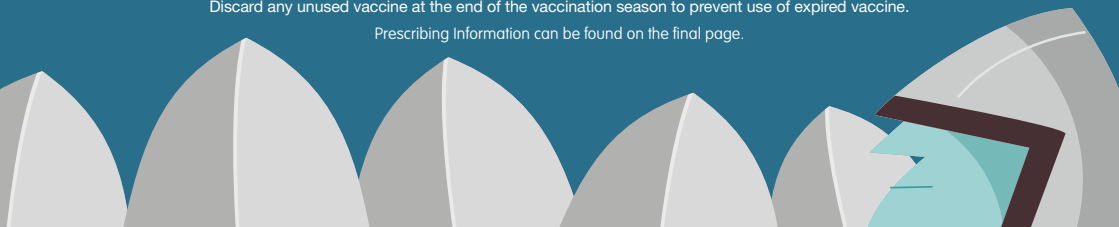
AstraZeneca

Administration guide

Fluenz Tetra

nasal spray, suspension
influenza vaccine
(live attenuated, nasal)

Flu protection without the injection



Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to AstraZeneca by visiting https://aereporting.astrazeneca.com or by calling 0800 783 0033.

Discard any unused vaccine at the end of the vaccination season to prevent use of expired vaccine.

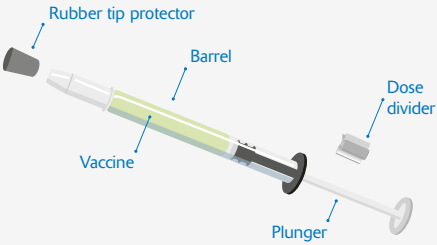
Prescribing Information can be found on the final page.

Administration of Fluenz® Tetra nasal spray vaccine[1]

Fluenz Tetra is administered as a nasal spray; **it must not be injected.**

1 Check the vaccine

Before the vaccine is administered:

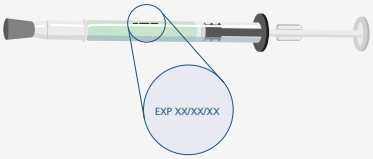


Check its appearance

This can vary, but should fit the following description: colourless to pale yellow, clear to opalescent suspension with or without small white particles.

Check the expiry date

The vaccine has a shelf life of 18 weeks. Always check the expiry date (day, month and year) on individual sprayers before administration. Discard any unused vaccine at the end of the vaccination season to prevent the use of expired vaccine.



2 Prepare the applicator

Prepare the applicator by removing the rubber tip protector.

Do not remove the dose-divider clip at the other end of the applicator. This splits the 0.2 ml dose so that an equal 0.1 ml quantity can be delivered to both nostrils.

3 Position the applicator

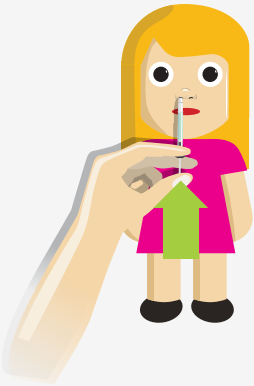
With the recipient in an upright position, place the tip just inside the first nostril to ensure the vaccine is delivered into the nose.

4 Depress the plunger

With a single motion, depress the plunger **as quickly as possible** until the dose-divider clip stops it going any further.

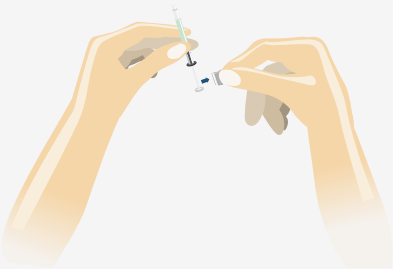
The recipient can breathe normally when they are receiving the vaccine, they do not have to actively inhale or sniff.

Please note: The vaccine does not need to be re-administered if the patient sneezes, or blows their nose following administration.[2]



5 Remove the dose-divider clip

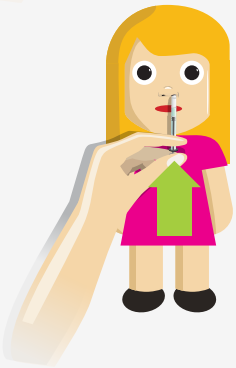
In order to administer the vaccine to the second nostril, pinch the dose-divider clip to remove it from the applicator.



6 Spray into the other nostril

Place the tip just **inside the second nostril** and with a single motion depress the plunger **as quickly as possible** to deliver the remaining 0.1ml dose of the vaccine.

Make sure any used product or waste material is disposed of in accordance with local requirements for medical waste.



Flu protection without the injection

Fluenz Tetra

nasal spray, suspension
influenza vaccine
(live attenuated, nasal)

Administration FAQs

Q **When should a second dose be administered?**

A The Summary of Product Characteristics for Fluenz Tetra states that for children who have not previously been vaccinated against seasonal influenza, a second dose of Fluenz Tetra should be given after an interval of at least 4 weeks.[1]

The use of Fluenz Tetra should be based on official recommendations.[1] Please refer to The Green Book; Chapter 19 for guidance where these differ to the Fluenz Tetra licensed indication.[2]

Q **What happens if the recipient receives too much or too little vaccine?**

A If a recipient receives too much, or too little, vaccine this is classed as an adverse event and should be reported. Reporting forms and information can be found at **www.mhra.gov.uk/yellowcard**. Adverse events should also be reported to AstraZeneca on 0800 783 0033.

In occasional reports, where twice the recommended dose of the trivalent Fluenz vaccine has been administered, adverse reactions reported were similar to those seen with the recommended single dose.

Q Can I administer this vaccine?

A Severely immunosuppressed people should not administer the vaccine as the risk of infection from the environment, while expected to be low, is unknown.[2]

Other healthcare workers who have less severe immunosuppression or are pregnant should follow normal clinical practice to avoid inhaling the vaccine and ensure that they themselves are appropriately vaccinated.[2]

For full Prescribing Information please see the SmPC available at www.medicines.org.uk

References

1. Fluenz Tetra. Fluenz Tetra nasal spray suspension Influenza vaccine (live attenuated, nasal) Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/3296/smpc2).

2. Department of Health. Immunisation Against Infectious Disease. (The Green Book.) Chapter 19: Influenza. London: The Stationery Office. 2019. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/733840/Influenza_green_book_chapter19.pdf.

AstraZeneca

Prescribing Information

FLUENZ® TETRA nasal spray suspension Influenza vaccine (live attenuated, nasal)
Consult Summary of Product Characteristics before prescribing.
Indication: Prophylaxis of influenza in individuals 24 months to less than 18 years of age. **Presentation:** Nasal spray, suspension. **Dosage and administration:** 0.2ml (administered as 0.1ml per nostril). Children not previously vaccinated against seasonal influenza should be given a second dose after an interval of at least 4 weeks. Should not be used in individuals below 24 months of age because of safety concerns. *Method of administration:* Nasal administration only. **Do not inject Fluenz Tetra.** **Contraindications:** Hypersensitivity to the active substances, any of the excipients (e.g. gelatin), gentamicin (a possible trace residue). Severe allergic reaction (e.g. anaphylaxis) to eggs or to egg proteins (e.g. ovalbumin). Children and adolescents who are clinically immunodeficient due to conditions or immunosuppressive therapy: (acute and chronic leukaemias; lymphoma; symptomatic HIV infection; cellular immune deficiencies; and high-dose corticosteroids). Not contraindicated for use in individuals with asymptomatic HIV infection; or individuals who are receiving topical/inhaled corticosteroids or low-dose systemic corticosteroids or those receiving corticosteroids as replacement therapy, e.g. for adrenal insufficiency. Contraindicated in children and adolescents younger than 18 years of age receiving salicylate therapy because of the association of Reye's syndrome with salicylates and wild-type influenza infection. **Warnings and precautions:** Clearly record name and batch number of administered product to improve traceability. Medical treatment and supervision should always be readily available in case of an anaphylactic event following administration. Fluenz Tetra should not be administered to children and adolescents with severe asthma or active wheezing because these individuals have not been adequately studied in clinical studies. Do not administer to infants and toddlers below 24 months of age because of safety concerns regarding increased rates of hospitalisation and wheezing in this population. Vaccine recipients should be informed that Fluenz Tetra is an attenuated live virus vaccine and has the potential for transmission to immunocompromised contacts. Vaccine recipients should attempt to avoid, close association with severely immunocompromised individuals (e.g. bone marrow transplant recipients requiring isolation) for 12 weeks following vaccination. Where contact is unavoidable, the potential risk of transmission of the influenza vaccine virus should be weighed against the risk of acquiring and transmitting wild-type influenza virus. No data exists regarding the safety in children with unrepaired craniofacial malformations. Drug interactions: Salicylates must not be used for 4 weeks following vaccination unless medically indicated. Co-administration of trivalent Fluenz with the live attenuated vaccines: No clinically meaningful changes in immune responses to measles, mumps, varicella, orally-administered poliovirus or trivalent Fluenz have been observed. Immune response to rubella vaccine was significantly altered. This might not be of clinical relevance with the two dose immunisation schedule of the rubella vaccine. Fluenz Tetra (influenza vaccine-live attenuated, nasal) is identical to trivalent Fluenz with the only difference being the addition of a fourth strain (a second B strain) to Fluenz Tetra. Co-administration of Fluenz Tetra with inactivated vaccines has not been studied. Concurrent use with antiviral agents active against influenza A and/or B viruses has not been evaluated. Based upon the potential for influenza antiviral agents to reduce the effectiveness of Fluenz Tetra, it is recommended not to administer the vaccine until 48 hours after the cessation of influenza antiviral therapy. Administration of influenza antiviral agents within two weeks of vaccination may affect the response of the vaccine. If influenza antiviral agents and Fluenz Tetra are administered concomitantly, revaccination should be considered based on clinical judgment. Fertility, Pregnancy and Lactation: Not recommended during pregnancy. Should not be used during breast-feeding. No data on the effects of Fluenz Tetra on male and female fertility. **Undesirable effects:** Refer to SmPC for complete information on side effects. Very common: decreased appetite, nasal congestion/rhinorrhoea, malaise. Common: headache, myalgia, pyrexia. Uncommon: hypersensitivity reactions (including facial oedema, urticaria and very rare anaphylactic reactions), epistaxis, rash. Very rare reports of Guillain-Barré syndrome and exacerbation of symptoms of Leigh syndrome (mitochondrial encephalomyopathy) have also been observed in the post-marketing setting. **Legal category:** POM. **Marketing authorisation number:** EU/1/13/887/004 **Presentation & basic NHS cost:** Fluenz Tetra nasal spray suspension pack of 10: £180.00 **Marketing Authorisation Holder:** AstraZeneca AB, SE-151 85 Södertälje, Sweden **Further information is available from:** AstraZeneca UK Limited, 600 Capability Green, Luton, LU1 3LU, UK.
FLUENZ is a trademark of the AstraZeneca group of companies.
Date of preparation: 03/2020
INF 20 0002

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to AstraZeneca by visiting https://aereporting.astrazeneca.com or by calling 0800 783 0033.

Date of preparation: August 2020. GB-22543