Pre-administration checklist for Fluenz™ Tetra nasal spray, suspension influenza vaccine (live attenuated, nasal)

AstraZeneca

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.

The checklist is to be used as a guide and does not substitute clinical judgement. The use of Fluenz Tetra should be based on official recommendations.[1]

- ☐ **1.** Is the recipient at least 24 months and <18 years old?
- ☐ **2.** Is the recipient allergic to any of the following?
  - ☐ Severe allergic reaction (e.g. anaphylaxis) to eggs or to egg proteins (e.g. ovalbumin)
  - ☐ Gentamicin
  - ☐ Gelatine (porcine, Type A)
  - ☐ Sucrose
  - ☐ Dipotassium phosphate
  - ☐ Potassium dihydrogen phosphate
  - ☐ Arginine hydrochloride
  - ☐ Monosodium glutamate monohydrate
  - ☐ Water for injections
- ☐ **3.** Is the recipient clinically immunodeficient?
- ☐ **4.** Is the recipient in close contact with people who are severely immunodeficient?
- ☐ **5.** Does the recipient have severe asthma or active wheezing?
- ☐ **6.** Is the recipient on salicylate therapy (e.g. aspirin)?
- ☐ **7.** Is the recipient pregnant or breast-feeding?
- ☐ **8.** Is the recipient receiving influenza antivirals?

The following pages will take you through the reasons why you need to ask these questions, before administering Fluenz Tetra

Flu protection without the injection

Fluenz™ Tetra

nasal spray, suspension influenza vaccine

(live attenuated, nasal)

The content of this checklist is intended for UK healthcare professionals only

Prescribing Information can be found on page 6.

1

Age: Is the recipient at least 24 months and less than 18 years old?

Fluenz Tetra is licensed to be given to children and adolescents who are at least 24 months and less than 18 years of age.[1]

Fluenz Tetra cannot be given to children under 24 months.[1]
A clinical trial showed an increase in hospitalisations for infants and toddlers aged 6–11 months and an increased incidence of wheezing in infants and toddlers aged 6–23 months compared with an injectable influenza vaccine.[1]

Please note:
These trends are isolated to the above age groups.[1]

2

Is the recipient allergic to any of the following?[1]

- Severe allergic reaction (e.g. anaphylaxis) to eggs or to egg proteins (e.g. ovalbumin)
- Gentamicin
- Gelatine (porcine, Type A)
- Sucrose
- Dipotassium phosphate
- Potassium dihydrogen phosphate
- Arginine hydrochloride
- Monosodium glutamate monohydrate
- Water for injections

Fluenz Tetra must not be given to children or adolescents who are hypersensitive (allergic) to any of the above, as they are present in this vaccine either as an ingredient or a trace residue.[1]

Hypersensitivity reactions (including facial oedema and urticaria) with Fluenz Tetra are uncommon (≥ 1/1,000 to < 1/100).[1] However as with all vaccines, appropriate medical treatment and supervision should be at hand in case of anaphylactic reaction: these have been reported as very rare (<1/10,000).[1]

Why eggs?

As the influenza strains are grown in hens' eggs, this vaccine may contain traces of egg proteins, e.g. ovalbumin.[1]

Why gentamicin?

Gentamicin may be present in this vaccine as a trace residue.[1]

Gentamicin is an antibiotic in the aminoglycoside class; it is not in the same antibiotic class as penicillin.[2,3]

What about other potential allergens?

Thiomersal

This vaccine is thiomersal-free.[4]

Latex

There is no latex in the raw materials of this vaccine or in any components of the sprayer. However, it is possible this vaccine or sprayer could have been exposed to latex during the packaging process.[4]

3

Is the recipient clinically immunodeficient?

Children and adolescents who are clinically immunodeficient or receiving immunosuppressive therapy must not be given Fluenz Tetra, this includes:[1]*

- Acute and chronic leukaemias
- Lymphoma
- Symptomatic HIV infection
- Cellular immune deficiencies
- High-dose corticosteroids*

* This is not an exhaustive list. The use of Fluenz Tetra should be based on official recommendations.

4

Is the recipient in close contact with people who are severely immunodeficient?

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, whenever possible, close association with severely immunocompromised individuals (e.g. bone marrow transplant recipients requiring isolation) for 1-2 weeks following vaccination.[1]

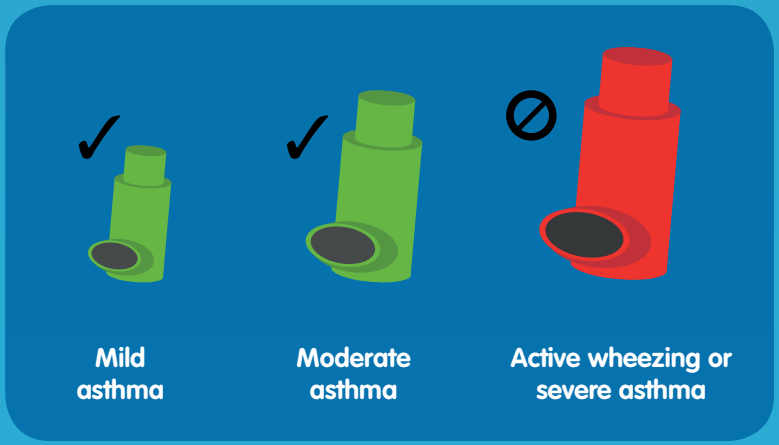
Peak incidence of vaccine virus recovery occurred 2-3 days post-vaccination in Fluenz clinical studies. In circumstances where contact with severely immunocompromised individuals is unavoidable, the potential risk of transmission of the influenza vaccine virus should be weighed against the risk of acquiring and transmitting wild-type influenza virus.[1]

5

Does the recipient have severe asthma or active wheezing?

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.[1]

Data in children and adolescents with chronic conditions other than mild-to-moderate asthma are limited.[1]



6

Is the recipient on salicylate therapy (e.g. aspirin)?

Children and adolescents receiving salicylate therapy (e.g. aspirin) must not be given this vaccine, as there is an association between the use of salicylates during influenza infection and Reye's syndrome.[1]

For the same reason, salicylates must not be given for 4 weeks following vaccination unless medically indicated.[1]

7

Is the recipient pregnant or breast-feeding?

Fluenz Tetra is not recommended during pregnancy and should not be used during breast-feeding.[1]

No data exist regarding the possible effects of Fluenz Tetra on male and female fertility.[1]

8

Is the recipient receiving influenza antivirals?

Influenza antivirals may potentially affect the effectiveness of this vaccine.[1] Therefore, this vaccine should not be administered until at least 48 hours after influenza antivirals are stopped.[1]

Influenza antivirals may also affect the response to this vaccine if taken in the two weeks following vaccination.[1]

If this vaccine and influenza antivirals are administered together it may be worth considering revaccination based on clinical judgement.[1]

Advice for faith communities

This nasal spray flu vaccine contains a highly processed form of gelatine (porcine - derived from pigs),[1] which is used globally in many medicines.[5]

Some faith groups accept the use of porcine gelatine in medical products[5] – the decision is, of course, up to the parents or guardians of your patient.

For further information about porcine gelatine and the nasal influenza vaccine, see:[5]

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/751199/Vaccines_porcine_gelatine.pdf

References

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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 FLUENZ TETRA with the live attenuated vaccines: No clinically meaningful changes in immune responses to measles, mumps, varicella, orally-administered poliovirus or FLUENZ TETRA 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. 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, headache, nasal congestion/rhinorrhoea, malaise. Common: 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.
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