

Package leaflet: Information for the user

Fluad Tetra, suspension for injection in pre-filled syringe Influenza vaccine (surface antigen, inactivated, adjuvanted)

▼ 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 you receive this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

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

Fluad Tetra is a vaccine against flu (influenza).

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 flu.

Fluad Tetra is used to prevent flu in elderly adults of 65 years of age and older.

The vaccine targets four strains of influenza virus following the recommendations by the World Health Organisation for the xxxx/xxxx season.

2. What you need to know before you receive Fluad Tetra

You should not receive Fluad Tetra

- if you are allergic to
 - the active ingredients or any of the other ingredients of this medicine (listed in section 6)
 - egg or chicken proteins (such as ovalbumin), kanamycin and neomycin sulphate, formaldehyde, cetyltrimethylammonium bromide (CTAB) and hydrocortisone, which are trace residues from the manufacturing process.
- If you have had a severe allergic reaction (e.g. anaphylaxis) to previous influenza vaccination.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before receiving Fluad Tetra

BEFORE receiving the vaccine

- Your doctor or nurse will make sure that appropriate medical treatment and supervision is readily available in case of a rare anaphylactic reaction (a very severe allergic reaction with symptoms

such as difficulty in breathing, dizziness, a weak and rapid pulse and skin rash) following the administration. This reaction may occur with Flud Tetra as with all vaccines that are injected.

- You should tell your doctor if you have an acute illness associated with fever. Your doctor may decide to delay your vaccination until your fever is gone.
- You should tell your doctor if your immune system is impaired, or if you are undergoing treatment which affects the immune system, e.g. with medicine against cancer (chemotherapy) or corticosteroid medicines (see Section “Other medicines and Flud Tetra”).
- You should tell your doctor if you have a bleeding problem or bruise easily.
- Fainting can occur following, or even before, any needle injection, therefore tell the doctor or nurse if you fainted with a previous injection.

As with all vaccines, Flud Tetra may not fully protect all persons who are vaccinated.

Children

Flud Tetra is not recommended for use in children.

Other medicines and Flud Tetra

Tell your doctor or nurse if you are using, have recently used or might use any other medicines, including medicines obtained without a prescription or if you have recently received any other vaccine.

Pregnancy and breast-feeding

This vaccine is for use in elderly adults 65 years and older. It is not to be used in women who are, or may be, pregnant or breast-feeding.

Driving and using machines

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

Flud Tetra contains potassium and sodium

This vaccine contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially ‘sodium free’.

This vaccine contains potassium, less than 1 mmol (39 mg) per dose, i.e. essentially ‘potassium free’.

3. How Flud Tetra is given

Flud Tetra is given by your doctor or nurse as an injection into the muscle at the top of the upper arm (deltoid muscle).

Adults of 65 years of age and older:

One dose of 0.5 ml

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects have been reported during clinical trials in adults 65 years of age and older.

Mild side effects

Very common (may affect more than 1 in 10 people):

- Pain at injection site
- Fatigue
- Headache

Common (may affect up to 1 in 10 people):

- Joint pain (arthralgia)
- Muscular pain (myalgia)
- Redness at injection site (erythema)
- Hardening of the skin at injection site (induration)
- Diarrhoea
- Shivering
- Nausea
- Loss of appetite
- Bruising at injection site (ecchymosis)
- Flu-like symptoms

Uncommon (may affect up to 1 in 100 people):

- Vomiting
- Fever ($\geq 38^{\circ}\text{C}$)

Most side effects were mild or moderate and went away within 3 days of appearing.

Next to the above side effects, the following side effects occurred occasionally during general use of another vaccine similar to Fluad Tetra.

- reduction in the number of certain types of particles in the blood called platelets; a low number of these can result in excessive bruising or bleeding (thrombocytopenia); swelling of the glands in the neck, armpit or groin (lymphadenopathy)
- swelling, pain and redness at the injection site extending to more than 10 cm and lasting more than one week (Injection site cellulitis-like reaction)
- extensive swelling of injected limb lasting more than one week.
- allergic reactions:
 - sudden fall in blood pressure due to severe allergic reactions that in rare cases can lead to failure of the circulatory system to maintain adequate blood flow to the different organs (shock),
 - swelling most apparent in the head and neck, including the face, lips, tongue, throat or any other part of the body (angioedema).
- muscular weakness
- pain on the nerve path (neuralgia), unusual feeling of touch, pain, heat and cold (paraesthesia), fits (convulsions), neurological disorders that may result in stiff neck, confusion, numbness, pain and weakness of the limbs, loss of balance, loss of reflexes, paralysis of part or all the body (encephalomyelitis, neuritis, Guillain-Barré Syndrome)
- skin reactions that may spread throughout the body including itchiness of the skin (pruritus, urticaria), rash
- severe skin rash (erythema multiforme)
- blood vessel swelling that may cause skin rashes (vasculitis) and temporary kidney problems

Reporting of side effects

If you get any side effects, talk to your health care professional. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fluad Tetra

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

Store in a refrigerator (2 °C to 8 °C). Do not freeze. Discard if the vaccine has been frozen. Keep the pre-filled syringe in the outer carton in order to protect from light.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

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 Fluad Tetra contains

The active substances are:

Influenza virus surface antigens (haemagglutinin and neuraminidase), inactivated, of the following strains*:

	per 0.5 ml dose
A/xxxxx (H1N1) - like strain (<i>reassortant used</i>)	15 micrograms HA**
A/xxxxx (H3N2) - like strain (<i>reassortant used</i>)	15 micrograms HA**
B/xxxxx – like strain (<i>reassortant used</i>)	15 micrograms HA**
B/xxxxx – like strain (<i>reassortant used</i>)	15 micrograms HA**

*propagated in fertilised hens' eggs from healthy chicken flocks and adjuvanted with MF59C.1

**haemagglutinin

This vaccine complies with the WHO recommendations (Northern Hemisphere) and EU recommendation for the xxxx/xxxx season.

MF59C.1 is included in this vaccine as an adjuvant. Adjuvants are substances included in certain vaccines to accelerate, improve and/or prolong the protective effects of the vaccine. MF59C.1 is an adjuvant that contains per 0.5 ml dose: squalene (9.75 mg), polysorbate 80 (1.175 mg), sorbitan trioleate (1.175 mg), sodium citrate (0.66 mg) and citric acid (0.04 mg).

The other ingredients are:

sodium chloride, potassium chloride, potassium dihydrogen phosphate, disodium phosphate dihydrate, magnesium chloride hexahydrate, calcium chloride dihydrate and water for injections.

What Fluad Tetra looks like and contents of the pack

Fluad Tetra is a suspension for injection in a pre-filled (ready to use) syringe. Fluad Tetra is a milky-white suspension. A single syringe contains 0.5 ml of suspension for injection. Fluad Tetra is available in packs containing 1 or 10 pre-filled syringes with or without needles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Seqirus Netherlands B.V.
Paasheuvelweg 28
1105 BJ Amsterdam
Netherlands

Manufacturers

Seqirus Vaccines Limited
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This leaflet was last revised in {MM/YYYY}.

Other sources of information

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

The following information is intended for healthcare professionals only:

Appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following the administration of the vaccine.

Gently shake before use. After shaking, the normal appearance of the vaccine is a milky white suspension.

The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine.

When using a pre-filled syringe supplied without a needle, remove the tip cap from the syringe and then attach a suitable needle for administration. For Luer Lock syringes, remove the tip cap by unscrewing it in a counter-clockwise direction. Once the tip cap is removed, attach a needle to the syringe by screwing it on in a clockwise direction until it locks. Once the needle is locked in place, remove the needle protector and administer the vaccine.