PACKAGE LEAFLET: INFORMATION FOR THE USER

Flucelvax® Tetra

Suspension for injection in pre-filled syringe

Influenza vaccine (surface antigen, inactivated, prepared in cell cultures)

▼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 Flucelvax Tetra is and what it is used for

Flucelvax Tetra is a vaccine against flu (influenza).
Flucelvax Tetra is prepared in cell cultures, and, therefore, is egg-free.
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.

Flucelvax Tetra is used to prevent flu in adults and children from 9 years of age.

The vaccine targets four strains of influenza virus following the recommendations by the World Health Organisation for the 2020/2021 season.

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

You should not receive Flucelvax Tetra:
If you are allergic to:
- the active ingredients or any of the other ingredients of this medicine (listed in section 6)
- beta-propiolactone, cetyltrimethylammonium bromide, or polysorbate 80, which are trace residues from the manufacturing process.

Adults and children from 9 years of age:
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 and during general use:

Very serious side effects
Tell your doctor immediately or go to the casualty department at your nearest hospital if you experience the following side effect – you may need urgent medical attention or hospitalisation:

- difficulty in breathing, dizziness, a weak and rapid pulse and skin rash which are symptoms of an anaphylactic reaction (a very severe allergic reaction)

Serious side effects
Tell your doctor immediately if you experience any of the following side effects – you may need medical attention:

- Extensive swelling of injected limb

Mild side effects
Very common (may affect more than 1 in 10 people):
- Injection site pain, reddening, hardening or swelling at the site of the injection
- Headache
- Muscle pain
- Tiredness

Hardening or swelling at the site of the injection, headache, muscle pain, and fatigue were common in the elderly.

Common (may affect up to 1 in 10 people):
- Nausea, vomiting, diarrhoea
- Loss of appetite
- Joint pain
- Bruising
- Shivering

Vomiting was uncommon in the elderly

Uncommon (may affect up to 1 in 100 people):
- Fever (≥ 38 °C)

Fever was common in adolescents and children.

Not known (cannot be estimated from the available data):
- Numbness and tingling sensation
- Generalised skin reactions including itching, bumps on the skin or non-specific rash

Reporting of side effects
If you get any side effects, talk to your healthcare professional. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before receiving Flucelvax 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 Flucelvax 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 Flucelvax 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, Flucelvax Tetra may not fully protect all persons who are vaccinated.

Other medicines and Flucelvax 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.

Flucelvax Tetra may be given at the same time as other vaccines.

Pregnancy and breast-feeding
Pregnancy:
Tell your doctor if you are pregnant, think you may be pregnant or are planning to have a baby. Influenza vaccinations can be used at any stage of pregnancy.

Breast-feeding:
Use of Flucelvax Tetra during breast-feeding has not been studied. Flucelvax Tetra may be used during breast-feeding.

Driving and using machines
Flucelvax Tetra has no or negligible effect on your ability to drive and use machines.

Flucelvax Tetra contains sodium chloride and potassium chloride
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 Flucelvax Tetra is given

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

5. How to store Flucelvax Tetra

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

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

Do not use this vaccine 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 Flucelvax Tetra contains
- The active substances are influenza virus surface antigens (haemagglutinin and neuraminidase), inactivated, of the following strains*:

A/Hawaii/70/2019 (H1N1)pdm09-like strain (A/Nebraska/14/2019, wild type) 15 micrograms HA**
A/Hong Kong/45/2019 (H3N2)-like strain (A/Delaware/39/2019, wild type) 15 micrograms HA**
B/Washington/02/2019-like strain (B/Darwin/7/2019, wild type) 15 micrograms HA**
B/Phuket/3073/2013-like strain (B/Singapore/INFTT-16-0610/2016, wild type) 15 micrograms HA**

per 0.5 ml dose
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* propagated in Madin Darby Canine Kidney (MDCK) cells (this is the special cell culture in which the influenza virus is grown);
** haemagglutinin

- This vaccine complies with the World Health Organisation (WHO) recommendation (northern hemisphere) and EU recommendation for the 2020/2021 season.

The other ingredients are: sodium chloride, potassium chloride, magnesium chloride hexahydrate, disodium phosphate dihydrate, potassium dihydrogen phosphate and water for injections.

What Flucelvax Tetra looks like and contents of the pack
Flucelvax Tetra is a suspension for injection in a pre-filled syringe (ready to use syringe).
Flucelvax Tetra is a clear to slightly opalescent suspension.
A single syringe contains 0.5 ml of suspension for injection.
Flucelvax Tetra is available in packs containing 1 pre-filled syringe with or without needle or 10 pre-filled syringes with or without needles.
Not all pack sizes may be marketed.

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Seqirus Netherlands B.V.
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Netherlands

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

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This leaflet was last revised in 08/2020.

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

Seqirus™