NEW ZEALAND CONSUMER MEDICINE INFORMATION

INFLUVAC® TETRA

Inactivated influenza vaccine

Suspension for injection 60 microgram per 0.5 mL

Mylan

What is in this leaflet

This leaflet answers some common questions about Influvac Tetra.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you having Influvac Tetra against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Influvac Tetra is used for

Influvac Tetra is used to prevent certain types of influenza (commonly called flu). The vaccine works by causing the body to produce its own protection (antibodies) against four different types of influenza virus.

Each year new types of influenza virus can appear, so every year Influvac Tetra is changed to contain fragments of the new types of virus. Therefore, influenza vaccination is recommended every year.

Please note that Influvac Tetra will only protect you against the four types of influenza virus used to make the vaccine. It will not protect you from influenza caused by other types of influenza virus or from infections with other agents causing flu-like symptoms (such as the common cold).

Influenza is an infectious illness. Influenza is spread by small droplets from the nose, throat or mouth of an infected person. Symptoms of influenza begin 48 hours after coming into contact with the virus. These consist of chills, fever, generalised aches and pains, headache and respiratory symptoms (sore throat, runny nose, cough). The severity and type of symptoms can vary. Most people recover completely within a week. The risk of serious complications (e.g. pneumonia and death) is greater in very young, very old and chronically ill persons.

Influvac Tetra can be used in adults and in children over the age of 3 years.

For full details regarding recommendations for influenza vaccination, please refer to the relevant National Immunisation Guidelines.

Talk to your doctor if you have any questions.

Before you receive Influvac Tetra

When you must not receive it

Do not have Influvac Tetra if:

- you have had an allergic reaction to Influvac or Influvac Tetra, or any ingredient contained in this vaccine. The ingredients are listed at the end of this leaflet.
  Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.
- you have had an allergic reaction or become unwell after any other influenza vaccine (Fluvax, Fluarix, Fluvirin or Vaxigrip)
- you are allergic to chicken proteins such as in eggs or feathers
- you are allergic to gentamicin, formaldehyde, cetrimonium bromide or polysorbate 80
- you have an illness with a high temperature or acute infection.
  A minor infection such as a cold should not be a problem, but talk to your doctor or nurse about this before being vaccinated.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.
If it has expired or is damaged, return it to your pharmacist for disposal.

Talk to your doctor or nurse if you are not sure whether you should have Influvac Tetra.

Do not give this vaccine to anyone else.
Your doctor has prescribed it specifically for you.

Before you receive it

Tell your doctor if:

- you have been allergic to any other medicines, foods, dyes or preservatives
- you have had Influvac or Influvac Tetra before and become unwell. Tell your doctor, nurse or pharmacist before the next dose is given.
- you are pregnant or intend to become pregnant. Your

doctor will discuss with you the benefits and risks of having Influvac Tetra when pregnant.
- you are breast feeding. Your doctor will discuss the risks and benefits of vaccination, however the vaccine is not expected to cause problems for breastfed babies.
- you have ever had an illness affecting the nervous system, especially Guillain-Barre Syndrome (GBS). If you have had GBS, you may be more likely to develop GBS following influenza vaccination than someone who has never had GBS.
- you have any medical conditions, such as HIV, an immune deficiency condition or a bleeding disorder.

If you have not told your doctor about any of the above, tell him/her before you are given Influvac Tetra.

Taking other medicines

Tell your doctor, nurse or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop. Some medicines and Influvac Tetra may interfere with each other. These include:

- immunosuppressant medicines.

These medicines may be affected by Influvac Tetra. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How Influvac Tetra is given

The doctor, nurse or pharmacist will give Influvac Tetra as an injection.

Talk to your doctor, nurse or pharmacist if you have any concerns about how this vaccine is to be given.

How much is given

Adults and children over the age of 3 years: 0.5 mL

How it is given

The injection may be given in the upper arm muscle.

For some people with bleeding problems, the injection may need to be given under the skin (subcutaneously).

Influvac Tetra should never be given intravenously.

When it is given

Influvac Tetra is generally given as a single dose each year during autumn.

For some people, particularly those with low immunity, and children (aged 3-9 years) who are receiving influenza vaccination for the first time, a second dose should be given 4 weeks after the first dose. However, one dose is sufficient for most people and especially those who have been vaccinated against influenza in an earlier year.

If a dose is missed

Talk to your doctor or nurse and arrange another visit as soon as possible.

If you are given too much (overdose)

Given the nature of the product and the way it is administered, overdosage is unlikely.

However you can telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice if you think that you or anyone else may have been given too much Influvac Tetra.

After receiving Influvac Tetra

Things to be careful of

Be careful driving or operating machinery until you know how Influvac Tetra affects you.

Influvac Tetra should not normally interfere with your ability to drive a car or operate machinery. But in some people, vaccination can cause dizziness or light-headedness. Make sure you know how you react to Influvac Tetra before you drive a car, operate machinery, or do anything that could be dangerous if you are dizzy or light-headed.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well during or after having a dose of Influvac Tetra.

Influvac Tetra helps protect most people from influenza, but it may have unwanted side effects in a few people. All medicines and vaccines can have side effects. Sometimes they are serious; most of the time they are not. Some side effects may need medical treatment.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Most unwanted effects with Influvac Tetra are mild and usually clear up within a few days. These effects, as with other vaccines, generally occur around the injection site.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- redness, swelling, a hard lump, soreness, bruising or itching around the injection site
- fever, chills, headache, malaise (generally unwell)
- fatigue or drowsiness
- loss of appetite
- diarrhoea or vomiting
- muscle aches and pains.

The above side effects are usually mild and short-lived.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital, if you notice any of the following:

- swelling of limbs, face, eyes, inside of nose, mouth or throat
- shortness of breath, breathing or swallowing difficulties
- hives, itching (especially of the hands or feet), reddening of skin (especially around the ears), or severe skin reactions
- unusual tiredness or weakness that is sudden and severe.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

As with all vaccines given by injection there is a very small risk of serious allergic reaction. Allergy to Influvac Tetra is rare. Any such severe reactions will usually occur within the first few hours of vaccination.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur during or soon after a dose of vaccine.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Storage

Influvac Tetra is usually stored at the pharmacy or at the doctor's clinic or surgery.

If you need to store the vaccine, always:

- **keep Influvac Tetra in the refrigerator stored between 2°C and 8°C. THE PACK SHOULD NEVER BE FROZEN. FREEZING DESTROYS THE VACCINE.**
- keep the vaccine out of the reach of children.
- keep Influvac Tetra in the original pack until it is time for it to be given.

Disposal

Ask your pharmacist what to do with any leftover Influvac Tetra that has expired or has not been used.

Product description

What it looks like

Influvac Tetra is a clear, colourless liquid.

Packs of 1 or 10 prefilled (0.5 mL) glass syringes.

Ingredients

Each 0.5 mL dose of Influvac Tetra contains four types of influenza virus fragments in a phosphate buffered salt solution.

- H1N1 strain 15 micrograms
- H3N2 strain 15 micrograms
- B/Yamagata strain 15 micrograms
- B/Victoria strain 15 micrograms

It also contains:

- calcium chloride dihydrate
- dibasic sodium phosphate dihydrate
- magnesium chloride hexahydrate
- monobasic potassium phosphate
- potassium chloride
- sodium chloride
- water for injections.

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

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

The vaccine may also contain limited quantities of ovalbumin, formaldehyde, cetrimonium bromide, sodium citrate, sucrose, gentamicin sulfate, tylosine tartrate, hydrocortisone and polysorbate 80 which are used during the manufacturing process.

Influvac Tetra is not made with any human blood or blood products, or any other substances of human origin.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Influvac Tetra is supplied in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: 0800 579 811

Date of Information

14 April 2021
(Based on datasheet dated 5 November 2020)