

INFLUVAC® TETRA

Quadrivalent Influenza Vaccine, surface antigen, inactivated (influenza virus haemagglutinin)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about INFLUVAC TETRA vaccine. It does not contain all the available information. It does not take the place of talking to your doctor, nurse or pharmacist. Please read it carefully and keep it for future reference.

All medicines and vaccines have risks and benefits. Your doctor, nurse or pharmacist has weighed the possible risks of you having INFLUVAC TETRA against the expected benefits.

Talk to your doctor, nurse or pharmacist if you have any concerns about receiving INFLUVAC TETRA.

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 children over the age of 3 years.

Talk to your doctor, nurse or pharmacist if you have any questions.

Before you receive Influvac Tetra

Do not have INFLUVAC TETRA if:

- you have had an allergic reaction to INFLUVAC TETRA, or any ingredient listed at the end of this leaflet
Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.
- you have had an allergic reaction or became unwell after

any other influenza vaccine (e.g. Fluvax, Vaxigrip, Fluarix Tetra etc.)

- you are allergic to chicken proteins such as in eggs or feathers.
- you are allergic to gentamicin
- you have a severe infection with a high temperature. Vaccination should be postponed until after you have recovered.
A minor infection such as a cold should not be a problem, but talk to your doctor, nurse or pharmacist about this before being vaccinated.
- the expiry date printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

Talk to your doctor, nurse or pharmacist if you are not sure whether you should have INFLUVAC TETRA.

Do not give this vaccine to anyone else.

This vaccine is prescribed specifically for you.

Before having INFLUVAC TETRA

Tell your doctor, nurse or pharmacist if:

- you have been allergic to any other medicines, foods, dyes or preservatives
- you have had INFLUVAC TETRA before and became 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 taking

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 breast-fed 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 an immune deficiency condition or a bleeding disorder.

Interactions with other medicines

Tell your doctor, nurse or pharmacist if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop, or have received another vaccine.

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 3 years of age: 0.5 mL

For children less than 9 years of age who have not previously been vaccinated, a second dose of 0.5 mL should be given after an interval of at least 4 weeks.

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 in autumn each year before the start of the influenza season.

Vaccination should be repeated every year as new types of influenza virus can appear each year.

If the dose is missed

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

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 had 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.

MILD EVENTS

Tell your doctor as soon as possible if you notice any of the following:

- redness, swelling, a hard lump, soreness, bruising or itching around the injection site
- fever, chills, headache, malaise (generally unwell)
- muscle aches and pains

MORE SERIOUS EFFECTS THAT MAY OCCUR RARELY

As with all vaccines given by injection there is a very small risk of serious allergic reaction. 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.

As with all vaccines given by injection there is a very small risk of such reactions. 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.**

Ask your pharmacist what to do with any left over 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 pre-filled (0.5 mL) glass syringes.

Ingredients

Each 0.5 mL dose of INFLUVAC TETRA contains 15 micrograms of each of the four types of influenza virus fragments in a phosphate buffered salt solution:

- A/Victoria/2570/2019 (H1N1)pdm09-like strain

- A/Hong Kong/2671/2019 (H3N2)-like strain
- B/Washington/02/2019-like (B/Victoria lineage) virus
- B/Phuket/3073/2013-like (B/Yamagata lineage) virus.

And:

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

The vaccine also contains limited quantities of egg protein (ovalbumin or chicken proteins), formaldehyde, cetrimeronium bromide, sodium citrate, sucrose, gentamicin sulfate, traces of tylosine tartrate, hydrocortisone and polysorbate 80.

INFLUVAC TETRA is not made with any human blood or blood products, or any other substances of human origin.

Sponsor

INFLUVAC TETRA is manufactured in The Netherlands for:

Mylan Health Pty Ltd
Level 1, 30 The Bond
30-34 Hickson Road
Millers Point, NSW 2000
Australia
Telephone: 1800 314 527

Registration numbers:

AUST R 292237

AUST R 292238

AUST R 281035

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