

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

INFLUVAC[®] TETRA
Quadrivalent influenza vaccine, surface antigen, inactivated
suspension for injection in pre-filled syringes

Read this carefully before you receive **INFLUVAC[®] TETRA**. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **INFLUVAC[®] TETRA**.

Serious Warnings and Precautions

- **INFLUVAC[®] TETRA should not be used in individuals who are allergic to eggs, previous doses of the flu vaccine, or any components of the flu vaccine.**

What is INFLUVAC[®] TETRA used for?

- INFLUVAC[®] TETRA is a vaccine used to prevent adults of 18 years of age and older from developing influenza (the flu).

How does INFLUVAC[®] TETRA work?

Like other influenza vaccines, INFLUVAC[®] TETRA causes the body to produce antibodies against the virus. This means that when your body is exposed to the flu virus, your body is able to defend itself. The antibodies stop the attacking virus. You cannot catch influenza from INFLUVAC[®] TETRA since it only contains portions of the inactivated virus, and not the whole live virus. Your body takes 10 to 21 days to produce antibodies after vaccination. Therefore, if you are exposed to influenza immediately before or after your vaccination, you could still develop the illness. The vaccine will not protect you against the common cold, even though some of the symptoms are similar to influenza. Influenza viruses change all the time, so different vaccines may be made every year. To stay protected against influenza, you need to be re-vaccinated every year before the winter season.

It is particularly important for some groups of people to be vaccinated. These include people with certain medical conditions, elderly people, people who are likely to be exposed to the infection and people on certain medications. If you are in doubt as to whether you should be vaccinated, talk to your local health care professionals.

INFLUVAC[®] TETRA complies with the World Health Organization (WHO) and National Advisory Committee on Immunization (NACI) recommendations for vaccination in the northern hemisphere for the 2019/2020 season.

What are the ingredients in INFLUVAC[®] TETRA?

Medicinal ingredients: The medicinal ingredient is surface antigens neuraminidase and hemagglutinin of the following viruses as recommended by WHO and the NACI: an A/Brisbane/02/2018 (H1N1)pdm09-like virus; an A/Kansas/14/2017 (H3N2)-like virus; a B/Colorado/06/2017-like virus (B/Victoria/2/87 lineage); and a B/Phuket/3073/2013-like virus (B/Yamagata/16/88 lineage).

Non-medicinal ingredients: Calcium chloride dihydrate, disodium phosphate dihydrate,

magnesium chloride hexahydrate, potassium chloride, potassium dihydrogen phosphate, sodium chloride, water for injection and trace amounts of cetyltrimethyl ammonium bromide, chicken protein, eggs, formaldehyde, gentamicin sulphate (or neomycin sulphate, polymyxin B sulphate), hydrocortisone, polysorbate 80, sodium citrate, sucrose and tylosine tartrate.

INFLUVAC® TETRA comes in the following dosage forms:

INFLUVAC® TETRA comes in a 0.5 mL pre-filled syringe for injection, containing neuraminidase and 15 mcg hemagglutinin of each of the following virus strains:

- A/Brisbane/02/2018 (H1N1)pdm09-like strain (A/Brisbane/02/2018, IVR-190)
- A/Kansas/14/2017 (H3N2)-like strain (A/Kansas/14/2017, NYMC X-327)
- B/Colorado/06/2017-like strain (B/Maryland/15/2016, NYMC BX-69A)
- B/Phuket/3073/2013-like strain (B/Phuket/3073/2013, wild type)

Do not use INFLUVAC® TETRA if:

- INFLUVAC® TETRA vaccine is made in eggs; therefore this vaccine should not be given to anyone with allergies and especially severe allergies (anaphylactic reactions) to chicken eggs or egg products.
- INFLUVAC® TETRA should not be given to people who have allergies to the active substances, to any of the excipients and to residues of eggs, chicken protein, formaldehyde, cetyltrimethylammonium bromide, polysorbate 80, or gentamicin. For a complete listing of excipients, see the DOSAGE FORMS, COMPOSITION AND PACKAGING section of the Product Monograph.
- Anyone who has experienced allergic reactions to a previous dose of influenza vaccine SHOULD NOT be vaccinated with INFLUVAC® TETRA.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you receive INFLUVAC® TETRA. Talk about any health conditions or problems you may have, including if you:

- BEFORE you use INFLUVAC® TETRA talk to your doctor or pharmacist if: you are allergic to eggs or egg-products; you are allergic to any of the following: formaldehyde, cetyltrimethylammonium bromide, polysorbate 80 or gentamicin; you have a fever, or you think you may be getting a fever; you had a serious reaction to any flu vaccine in the past; you have any known allergies; you have experienced any health problems; you are pregnant; you are currently on any medication (i.e., immunosuppressants, theophylline, anticoagulants such as warfarin).
- Fainting, feeling faint or other stress related reactions can occur following, or even before, any needle injection. Therefore, tell your doctor or nurse if you have experienced this kind of reaction with a previous injection.

Other warnings you should know about:

See above.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with INFLUVAC® TETRA:

- Immunosuppressants.

How to take INFLUVAC® TETRA:

INFLUVAC® TETRA should only be given by a health care professional.

Usual dose:

One dose of 0.5 mL pre-filled syringe containing neuraminidase and 15 mcg hemagglutinin per viral strain as recommended by WHO and NACI.

Adults: 0.5 mL, single dose.

INFLUVAC® TETRA comes as a 0.5 mL suspension, ready for intramuscular or deep subcutaneous injection. Allow the vaccine to reach room temperature before use. Shake well before use.

Overdose:

Overdosage is unlikely to have any bad effect.

If you think you have taken too much INFLUVAC® TETRA, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

Not applicable.

What are possible side effects from using INFLUVAC® TETRA?

These are not all the possible side effects you may feel when taking INFLUVAC® TETRA. If you experience any side effects not listed here, contact your healthcare professional.

Occasionally people have side effects with influenza vaccines. The most common of these are fever, feeling unwell, shivering, tiredness, headache, sweating, muscle or joint pain, and warmth. Skin reactions include redness, swelling, pain, ecchymosis (blue/black staining of the skin), a hardening of the skin at the injection site and itching.

These reactions will normally disappear without treatment in a day or two.

Rarely, neuralgia (nerve pain), paresthesia (numbness and tingling), convulsions (seizures) and temporary thrombocytopenia (a blood disorder) have been reported. In rare cases, allergic reactions may lead to shock.

Very rarely, vasculitis (inflammation of blood vessels) temporarily affecting the kidneys, neurological disorders (affecting the nerves and brain) such as encephalomyelitis, neuritis and Guillain Barré syndrome have been reported.

Allergic reactions (this might include but is not limited to breathing or swallowing difficulties, or swelling in the face or skin), and temporary enlargement of the lymph nodes have been reported.

If you think that you have a side effect not mentioned here, please tell your doctor or pharmacist.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Fever	X		
Feeling unwell			
Shivering	X		
Tiredness	X		
Headache	X		
Sweating	X		
Muscle or joint pain	X		
<u>Skin Reactions</u>	X		
Redness			
Swelling	X		
Pain	X		
Ecchymosis	X		
(blue/ black staining of the skin)	X		
Reddening of the skin at the injection site	X		
UNCOMMON			
Nerve pain		X	
Numbness and tingling		X	
Convulsions (seizures)		X	
Temporary thrombocytopenia (a blood disorder)		X	
Allergic reactions		X	
Inflammation of blood vessels temporarily affecting the kidneys		X	
Brain disorders		X	
Guillain Barré syndrome		X	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Suspected Side Effects

For the general public: Should you experience a side effect following immunization, please report it to your doctor, nurse, or pharmacist.

Should you require information related to the management of the side effect, please contact your healthcare provider. The Public Health Agency of Canada, Health Canada and BGP Pharma ULC cannot provide medical advice.

For healthcare professionals: If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (<https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization/form.html>) and send it to your local Health Unit.

Storage:

Store INFLUVAC® TETRA at 2 to 8°C (in a refrigerator).

Do not freeze. Store in the original package in order to protect from light.

Do not use after the expiry date.

This vaccine is effective against this year's 2019/2020 influenza virus.

Keep out of reach and sight of children.

If you want more information about INFLUVAC® TETRA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website](#); the manufacturer's website www.mylan.ca, or by calling 1-844-596-9526.

This leaflet was prepared by BGP Pharma ULC.

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