PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

INFLUVAC TETRA 2021, suspension for injection in pre-filled syringe

Influenza vaccine (surface antigen, inactivated)

Contains sugar (sucrose 0,0002 g).

Read all of this leaflet carefully because it contains important information for you or your child.

The vaccine is not for self-administration and must be administered by a professional healthcare provider.

Influvac Tetra is available without a doctor's prescription, for you or your child to protect against influenza (flu). Nevertheless, you still need to use Influvac Tetra carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Influvac Tetra with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What Influvac Tetra is and what it is used for
2. What you need to know before you or your child use Influvac Tetra
3. How to use Influvac Tetra
4. Possible side effects
5. How to store Influvac Tetra
6. Contents of the pack and other information

1. WHAT INFLUVAC TETRA IS AND WHAT IT IS USED FOR

Influvac Tetra is a vaccine. This vaccine helps to protect you or your child against influenza (flu), particularly in subjects who run a high risk of associated complications. Influvac Tetra is indicated in adults and children from 3 years of age. The use of Influvac Tetra should be based on official recommendations.

When a person is given the vaccine Influvac Tetra, the immune system (the body's natural defence

system) will produce its own protection (antibodies) against the disease. None of the ingredients in the vaccine can cause flu.

Flu is a disease that can spread rapidly and is caused by different types of strains that can change every year. Therefore, this is why you or your child might need to be vaccinated every year. The greatest risk of catching flu is during the cold months between October and March. If you or your child were not vaccinated in the autumn, it is still sensible to be vaccinated up until the spring since you or your child run the risk of catching flu until then. Your doctor will be able to recommend the best time to be vaccinated.

Influvac Tetra will protect you or your child against the four strains of virus contained in the vaccine from about 2 to 3 weeks after the injection.

The incubation period for flu is a few days, so if you or your child are exposed to flu immediately before or after your vaccination, you or your child could still develop the illness.

The vaccine will not protect you or your child against the common cold, even though some of the symptoms are similar to flu.

2. WHAT YOU NEED TO KNOW BEFORE YOU OR YOUR CHILD USE INFLUVAC TETRA

To make sure that Influvac Tetra is suitable for you or your child, it is important to tell your doctor or pharmacist if any of the points below apply to you or your child. If there is anything you do not understand, ask your doctor or pharmacist to explain.

Do not use Influvac Tetra

- If you or your child are allergic (hypersensitive) to:
  - the active substances, or
  - any of the other ingredients of Influvac Tetra (see section 6), or
  - any component that may be present in very small amounts such as eggs (ovalbumin or chicken proteins), formaldehyde, cetyltrimethylammonium bromide, polysorbate 80 or gentamicin (an antibiotic that is used to treat bacterial infections)
- If you or your child have an illness with a high temperature or acute infection, the vaccination shall be postponed until after you or your child have recovered.

Warnings and precautions

You or your child should tell your doctor before vaccination if you or your child have a poor immune response (immunodeficiency or taking medicines affecting the immune system).

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 or your child have experienced this kind of reaction with a previous injection.

Your doctor will decide if you or your child should receive the vaccine.

If, for any reason, you or your child have a blood test within a few days following a flu vaccination, please tell your doctor. This is because false positive blood test results have been observed in a few patients who had recently been vaccinated.

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

Other medicines and Influvac Tetra

- Please tell your doctor or pharmacist if you or your child are taking or have recently taken other vaccines or any other medicines, including medicines obtained without a prescription.
- Influvac Tetra can be given at the same time as other vaccines by using separate limbs. It should be noted that the side effects may be stronger.
- The immunological response may decrease in case of immunosuppressant treatment, such as corticosteroids, cytotoxic drugs or radiotherapy.

Pregnancy and breast-feeding

Tell your doctor or pharmacist if you are pregnant or think you may be pregnant.

Flu vaccines can be used in all stages of pregnancy. Larger datasets on safety are available for the second and third trimester, compared with the first trimester; however, data from worldwide use of flu vaccines do not indicate that the vaccine would have harmful effects on the pregnancy or the baby.

Influvac Tetra may be used during breast-feeding.

Your doctor/pharmacist will be able to decide if you should receive Influvac Tetra. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

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

Influvac Tetra contains sodium and potassium

This medicine contains less than 1 mmol sodium (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".

3. HOW TO USE INFLUVAC TETRA

Do not share medicines prescribed for you with any other person.

Always use Influvac Tetra exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

The usual dose is:

Adults receive one 0.5 ml dose.

Use in children and adolescents

Children from 3 - 17 years receive one 0.5 ml dose.

Children from 3 - 8 years, who have not previously been vaccinated with a seasonal influenza vaccine: a second dose should be given after an interval of at least 4 weeks.

For children less than 3 years of age the safety and efficacy of Influvac Tetra have not been established.

Method and/or route(s) of administration

Your healthcare provider will administer the recommended dose of the vaccine as an injection into the muscle or deep under the skin.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you take more Influvac Tetra than you should

Since a health care provider will administer Influvac Tetra, he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to take Influvac Tetra

Since a health care provider will administer Influvac Tetra, it is unlikely that the dose will be missed.

4. POSSIBLE SIDE EFFECTS

Influvac Tetra can cause side effects, although not everybody gets them.

Not all side effects reported for Influvac Tetra are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Influvac Tetra, please consult your health care provider for advice.

See your doctor straight away if you or your child experience any of the following side effects - you or your child may need urgent medical attention.

Severe allergic reactions (frequency unknown, occurred occasionally during general use of the trivalent influenza vaccine Influvac)

- that may lead to medical emergency with low blood pressure, rapid, shallow breathing, rapid heart rate

  and weak pulse, cold, clammy skin, dizziness, that may lead to collapse (shock)
- swelling most apparent in the head and the neck, including the face, lips, tongue, throat or any other part

  of the body and which may cause difficulty in swallowing or breathing (angioedema)

These are all serious side effects. You may need urgent medical attention.

During clinical trials with Influvac Tetra the following side effects have been observed:

Adults and elderly:

Very common: affects more than 1 in 10 people:

- headache [a]
- fatigue
- local reaction: vaccination site pain

[a] In elderly adults (≥ 61 years) reported as common

Common: affects 1 to 10 people in 100:

- sweating
- muscular pain (myalgia), joint pain (arthralgia)
- generally feeling unwell (malaise), shivering,
- local reactions: redness, swelling, bruising (ecchymosis), hardness (induration) around the area where the vaccine is injected.

Uncommon: affects between 1 in 1,000 and 1 in 100 people:

- fever

Children (3 - 17 years of age):

Side effects that occurred in children 3 - 5 years of age:

Very common: affects more than 1 in 10 people:

- irritability
- drowsiness
- appetite loss
- local reactions: vaccination site pain, redness, swelling, hardness (induration) around the area where the vaccine is injected

Common: affects 1 to 10 people in 100:

- sweating
- diarrhoea/vomiting
- fever
- local reaction: bruising (ecchymosis)

Side effects that occurred in children 6 - 17 years of age:

Very common: affects more than 1 in 10 people:

- headache
- gastrointestinal symptoms
- muscular pain (myalgia)
- fatigue, generally feeling unwell (malaise)
- local reactions: vaccination site pain, redness, swelling, hardness (induration) around the area where the vaccine is injected

Common: affects 1 to 10 people in 100:

- sweating
- joint pain (arthralgia)
- fever
- shivering
- local reaction: bruising (ecchymosis)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

For all age groups, most reactions usually occurred within the first 3 days following vaccination, resolved spontaneously within 1 to 3 days after onset. The intensity of these reactions was generally mild.

Next to the above side effects, the following side effects occurred occasionally during general use of the trivalent influenza vaccine Influvac:

Unknown frequency:

- skin reactions that may spread throughout the body including itchiness of the skin (pruritus, urticaria), rash
- blood vessel inflammation which may result in skin rashes (vasculitis) and in very rare cases in temporary kidney problems.
- pain situated on the nerve route (neuralgia), anomalies in the perception of touch, pain, heat and cold (paraesthesia), fits (convulsions) associated with fever, 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 Syndrom)
- temporary 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 (transient thrombocytopenia); temporary swelling of the glands in the neck, armpit or groin (transient lymphadenopathy)

Reporting of side effects

If you or your child get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the national reporting system.

By reporting side effects, you can help provide more information on the safety of Influvac Tetra.

5. HOW TO STORE INFLUVAC TETRA

Keep out of sight and reach of children.

Store Influvac Tetra in a refrigerator (2 °C to 8 °C). Do not freeze.

Store the product in the original package in order to protect from light.

Do not use Influvac Tetra after the expiry date which is stated on the carton after EXP. The expiry date

refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Influvac Tetra contains

The active substances are:

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

- A/Victoria/2570/2019 (H1N1)pdm09-like strain	
(A/Victoria/2570/2019, IVR-215)	15 micrograms HA **
- A/Hong Kong/2671/2019 (H3N2)-like strain	
A/Hong Kong/2671/2019, IVR-208	15 micrograms HA **
- B/Washington/02/2019-like strain	
(B/Washington/02/2019, wild type)	15 micrograms HA **
- B/Phuket/3073/2013-like strain	
(B/Phuket/3073/2013, wild type)	15 micrograms HA **
	per 0.5 ml dose

* propagated in fertilised hens'eggs from healthy chicken flocks

** haemagglutinin

This vaccine complies with the World Health Organisation (WHO) recommendation (southern hemisphere) and EU recommendation for the 2021 season.

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

What Influvac Tetra looks like and contents of the pack

Influvac Tetra is a suspension for injection presented in pre-filled syringe with / without needle (clear glass, type I). The glass syringe is closed at one end with a rubber plunger and at the other end with a rubber tip cap. The plunger consists of a grey coloured bromobutyl rubber compound. The plunger rod

consists of polypropylene and is screwed into the rubber plunger. Each syringe can only be used once.

Pack size of 1 or 10.

Not all pack sizes may be marketed.

Holder of Certificate of Registration:

Abbott Laboratories S.A. (Pty) Ltd

Abbott Place

219 Golf Club Terrace

Constantia Kloof, 1709

South Africa

This leaflet was last revised in

11 August 2020

Registration number:

52/30.1/0094

The following information is intended for medical or healthcare professionals only:

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine.

The vaccine should be allowed to reach room temperature. Shake before use.

Inspect visually prior to administration.

Do not use the vaccine if foreign particles are present in the suspension.

Remove the needle guard / cap.

Hold the syringe upright and expel the remaining air.

Do not mix with other medicinal products in the same syringe.

The vaccine is not to be injected directly into any blood vessel.

See also section 3: How to use Influvac Tetra