1.3.2 APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

INFLUVAC TETRA 2024, suspension for injection in pre-filled syringe

Influenza vaccine (surface antigen, inactivated)

Sugar free

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 health care provider.

INFLUVAC TETRA is available without a doctor's prescription, to protect you or your child 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

INFLUVAC TETRA is a vaccine. This vaccine helps to protect you or your child against influenza (flu), particularly in if you have a high risk of associated complications. INFLUVAC TETRA is indicated in adults and children from 6 months 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 May and September within the same year. 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 receives 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.

INFLUVAC TETRA should not be administered to you:

- If you or your child are allergic (hypersensitive) to the active substances, or any of the other

ingredients of INFLUVAC TETRA (listed in 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 has an illness with a high temperature (fever) or acute infection, the vaccination shall be postponed until after you or your child has recovered.

Warnings and precautions

Tell your doctor or health care provider before administration of this vaccine:

- If you or your child has a poor immune response (immunodeficiency or taking medicines affecting the immune system).
- If you or your child has a bleeding problem or bruise easily.
- 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 has 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 has 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.

Children and adolescents

INFLUVAC TETRA should not be given to children younger than 6 months of age.

Other medicines and INFLUVAC TETRA

Always tell your health care provider if you or your child are taking or have recently taken other vaccines or any other medicine. (This includes all complementary or traditional medicines.)

INFLUVAC TETRA can be given at the same time as other vaccines. However, it should be noted that the side effects may be more severe.

The body's immune response may decrease in case of treatment with corticosteroids (medicine used to treat swelling and inflammation resulting from allergies as well as allergic asthma), cytotoxic medicines or radiotherapy (used to treat cancer).

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving INFLUVAC TETRA.

Inactivated flu vaccines can be used in all stages of pregnancy.

INFLUVAC TETRA may be used during breastfeeding.

Driving and using machines

INFLUVAC TETRA has no or negligible influence on the ability to drive or use machines. However, it is not always possible to predict to what extent INFLUVAC TETRA may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which INFLUVAC TETRA affects you.

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 less than 1 mmol potassium (39 mg) per dose, i.e. essentially potassium free.

3. How INFLUVAC TETRA will be administered

You will not be expected to give yourself INFLUVAC TETRA. It will be given to you as an injection into the muscle or deep under the skin by a person who is qualified to do so.

The usual dose is:

Adults receive one 0,5 mL dose.

Use in infants, children and adolescents

Children from 6 months – 17 years receive one 0,5 mL dose.

Children younger than 9 years of age, 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 infants younger than 6 months of age: the safety and efficacy of INFLUVAC TETRA have not been established.

If you forget to receive 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.

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 receiving INFLUVAC TETRA, please consult your health care provider for advice.

See your doctor straight away if you or your child experiences 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. If you have them, you may have had a serious reaction to

INFLUVAC TETRA. You may need urgent medical attention or hospitalisation.

During clinical trials with INFLUVAC TETRA the following side effects have been observed:

Adults and elderly:

Very common (may affect more than 1 in 10 people):

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

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

Common (may affect up to 1 in 10 people):

- 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 (may affect up to 1 in 100 people):

- fever.

Children (6 months – 17 years of age):

Side effects that occurred in children 6 to 35 months of age:

Very common (may affect more than 1 in 10 people):

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

Common (may affect up to 1 in 10 people):

- local reaction: bruising (ecchymosis).

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

Very common (may affect more than 1 in 10 people):

- appetite loss
- irritability/fussiness
- drowsiness
- diarrhoea
- vomiting
- sweating
- fever
- local reactions: vaccination site pain, redness.

Common (may affect up to 1 in 10 people):

- local reaction: bruising (ecchymosis).

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

Very common (may affect more than 1 in 10 people):

- headache
- nausea
- abdominal pain
- sweating
- muscular pain (myalgia)
- fatigue
- fever
- generally feeling unwell (malaise)
- local reactions: vaccination site pain, redness.

Common (may affect up to 1 in 10 people):

- joint pain (arthralgia)
- 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 and 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 INFLUVAC TETRA and/or 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 syndrome)
- 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 gets any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the **6.04 Adverse Drug Reaction Report Form**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. 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 reach of children.
- Store in a refrigerator (2 °C to 8 °C).
- Do not freeze.
- Store 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/4897/2022 (H1N1)pdm09-like strain
(A/Victoria/4897/2022, IVR-238 — 15 micrograms HA **
- A/Thailand/8/2022 (H3N2)-like strain
(A/Thailand/8/2022, IVR-237) — 15 micrograms HA **
- B/Austria/1359417/2021-like strain

(B/Austria/1359417/2021, BVR-26)	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 and EU recommendation for the 2024 season.

The other ingredients are: calcium chloride dihydrate, disodium phosphate dihydrate, magnesium chloride hexahydrate, potassium chloride, potassium dihydrogen phosphate, sodium chloride 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 or 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:

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This leaflet was last revised in

5 February 2024

Registration number:

52/30.1/0094

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