PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

INFLUVAC SUBUNIT 2026 (INJECTION)

Influenza vaccine (surface antigen, inactivated)

Sugar free

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

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

- Keep this leaflet. You may need to read it again.
- Do not share INFLUVAC SUBUNIT 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 SUBUNIT is and what it is used for

INFLUVAC SUBUNIT is a vaccine.

The vaccine helps to prevent you from contracting influenza or flu, particularly if:

1. You are at high risk for influenza (flu) and its complications because of underlying medical conditions.
2. You are receiving regular medical care for conditions such as chronic lung and heart diseases, chronic kidney diseases, diabetes mellitus and similar disorders.
3. Your immune system is suppressed.
4. You are a resident of an old age home or chronic care rehabilitation institution.
5. You are a child on long-term aspirin therapy.
6. You are a medical or nursing staff member responsible for the care of high risk cases.
7. You are an adult or a child whose family contacts are of high risk cases.
8. You are over the age of 65 years.
9. You wish to protect yourself from the risk of contracting influenza (flu), especially in industrial settings, where large scale absenteeism could cause significant economic losses.

INFLUVAC SUBUNIT inactivated influenza vaccine will only offer protection against the three strains of the virus which are mentioned on the label within 2 to 3 weeks after taking the vaccine. The duration of immunity after vaccination varies, but is usually 6 – 12 months.
The vaccine will not protect you from common cold even though some symptoms are similar to influenza.

2. What you need to know before you or your child receives INFLUVAC SUBUNIT

INFLUVAC SUBUNIT should not be administered:

- If you or your child is allergic to the active substances, chicken protein, eggs or any of the other ingredients of INFLUVAC SUBUNIT (listed in section 6), or any component that may be present in very small amounts such as formaldehyde, cetyltrimethylammonium bromide, polysorbate or an antibiotic called gentamycin.
- If you or your child has a high fever or acute infection. Vaccination will be postponed until you

or your child has recovered.

Warnings and precautions

Tell your doctor or health care provider before you or your child is given the injection:

If you or your child has:

- Received any other injections to prevent diseases.
- A poor immune response (immunodeficiency or taking medicines that suppress your immune system).
- A bleeding problem or bruise easily.
- A blood test within a few days after a flu vaccination. False blood test results have been observed in some patients who had been recently vaccinated.

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.

As with all vaccines, INFLUVAC SUBUNIT may not fully protect all persons who are vaccinated.

Children

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

Other medicines and INFLUVAC SUBUNIT

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

INFLUVAC SUBUNIT can be given at the same time as other vaccines. However, side effects may be more severe.

The body’s immune response may decrease in case of treatment with medicines that suppress the immune system, such as 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 SUBUNIT.

INFLUVAC SUBUNIT can be used in all stages of pregnancy and during breastfeeding.

Driving and using machines

INFLUVAC SUBUNIT 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 SUBUNIT 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 SUBUNIT affects you.

INFLUVAC SUBUNIT contains sodium and potassium

This vaccine contains less than 1 mmol sodium (23 mg) and less than 1 mmol potassium (39 mg) per dose, i.e. essentially sodium-free and potassium-free.

3. How INFLUVAC SUBUNIT will be administered

This product is only for use by a health care professional and is not for self-administration.

The doctor or pharmacist will decide if you need the injection and when you should receive a follow up injection. This injection is only for intramuscular and subcutaneous administration. The injection should under no circumstances be injected into a vein.

The usual dose is:

Adults and children over 3 years: 1 dose (0,5 mL).

Use in children and adolescents:

Children 6 months to 3 years : ½ dose (0,25 mL).

Children less than 6 months: The safety and efficacy of INFLUVAC SUBUNIT in children less than 6 months have not been established.

Children who have never been vaccinated should receive a second dose of the same volume after an interval of at least 4 weeks.

Method of administration:

You will not be expected to give yourself INFLUVAC SUBUNIT. Your doctor or pharmacist will inject the recommended dose of INFLUVAC SUBUNIT into the muscle or deep under the skin.

If you receive more INFLUVAC SUBUNIT than you should

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

If you forget to receive INFLUVAC SUBUNIT

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

4. Possible side effects

INFLUVAC SUBUNIT can cause side effects.

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

If any of the following happens, tell your doctor or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching

- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to INFLUVAC SUBUNIT. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Common side effects:

Common means that between 1 and 10 patients in every 100 have reported this side effect.

Systemic reactions including:

- headache
- sweating
- muscle pain
- joint pain
- fever
- a feeling of general discomfort or uneasiness
- shivering
- fatigue.

These side effects usually disappear within 1 – 2 days without treatment.

Local reactions including:

- redness
- swelling
- pain
- a purplish patch caused by blood leaking into the skin
- firming of the area.

The following side effects occurred when the INFLUVAC SUBUNIT came to the market and the frequency is unknown:

- a temporary reduction in the number of the 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)

- allergic reactions, in rare cases leading to shock, swelling that affects deeper layers of the skin, often around the eyes and lips (angioedema)
- intense burning or stabbing pain along the course of the nerve (neuralgia), anomalies in the perception of touch, pain, heat and cold (paraesthesia), fever fit (febrile convulsions), neurological disorders, such as inflammation of the brain and spinal cord (encephalomyelitis), inflammation of a peripheral nerve or nerves, usually causing pain and loss of function (neuritis) and an acute disorder of the peripheral nerves, often preceded by a respiratory infection, causing weakness and often paralysis of the limbs (Guillain Barré syndrome)
- inflammation of the blood vessels which may result in skin rashes (vasculitis) associated in very rare cases with transient renal involvement
- generalised skin reactions including itching, hives or non-specific rash.

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

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of INFLUVAC SUBUNIT.

Abbott Laboratories South Africa Pharmacovigilance: pv.south-africa@abbott.com.

5. How to store INFLUVAC SUBUNIT

- Do not use this vaccine after the expiry date printed on the pack.
- Keep the vaccine in the original pack and store in a refrigerator (2 °C to 8 °C), avoid freezing.
- Protect from light.
- Shake well before use, a slight turbidity may occur.

- If you don't need to use this medicine anymore, take it to your doctor or nearest pharmacy who will dispose of it. Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).
- **KEEP OUT OF REACH OF CHILDREN.**

6. Contents of the pack and other information

What INFLUVAC SUBUNIT contains

Each 0,5 mL INFLUVAC SUBUNIT influenza vaccine contains influenza virus surface antigens (inactivated) (haemagglutinin and neuraminidase)* of strains:

A/Missouri/11/2025 (H1N1)pdm09-like strain	
(A/Switzerland/6849/2025, IVR-278)	15 µg HA**
A/Singapore/GP20238/2024 (H3N2)-like strain	
(A/Singapore/GP20238/2024, IVR-277)	15 µg HA**
B/Austria/1359417/2021-like strain	
(B/Austria/1359417/2021, BVR-26)	15 µg HA**

diluted in isotonic phosphate buffer of pH 7,2.

Sugar free.

* Propagated in fertilised hen's eggs from healthy chicken flocks.

** Haemagglutinin

*** Instructions for the wording of the strain information:

1. When the official strain is directly used: nothing added.

2. When the strain used is a strain like to the official one: - like strain used <actual strain >.

3. When the strain used is derived from the official one: - derived strain used <actual strain >.

4. When the strain used is derived from a strain like to the official one: - like strain used <actual strain> derived from <like strain>.

The strains of influenza used in the formulation are valid for 2026 only and comply with the WHO recommendations for the Southern hemisphere for 2026. It is likely that different antigenic variants will be recommended for 2027.

In order to make an injection, other ingredients have to be added. These other inactive ingredients are: calcium chloride dihydrate, disodium phosphate dihydrate, magnesium chloride hexahydrate, potassium chloride, potassium dihydrogen phosphate, sodium chloride and water for injection.

INFLUVAC SUBUNIT may contain traces of eggs (such as ovalbumin, chicken proteins), sodium citrate, sucrose, cetyl trimethyl ammonium bromide, formaldehyde, gentamicin sulphate, tylosine tartrate, polymyxin B sulphate, neomycin sulphate, hydrocortisone and polysorbate 80.

What INFLUVAC SUBUNIT looks like and contents of the pack

Clear colourless liquid.

0,5 mL suspension for injection in disposable pre-filled syringe with or without needle (glass, type I).

Pack of 1 or 10. Not all pack sizes may be marketed.

Holder of Certificate of Registration:

Abbott Laboratories S.A. (Pty) Ltd

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Constantia Kloof, 1709

South Africa

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27 August 1993

Name and address of manufacturer:

Abbott Biologicals B.V

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