PROFESSIONAL INFORMATION

SCHEDULING STATUS: S2

1. NAME OF THE MEDICINE

INFLUVAC SUBUNIT 2026 (INJECTION)

Influenza vaccine (surface antigen, inactivated)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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>.

INFLUVAC SUBUNIT inactivated influenza vaccine is an aqueous suspension containing the purified haemagglutinin and neuraminidase antigens prepared from influenza virus strains selected on the basis of current World Health Organisation recommendations.

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.

For a full list of excipients see section 6.1.

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.

3. PHARMACEUTICAL FORM

Suspension for injection in prefilled syringe.

Clear colourless liquid, filled in single-dose syringes.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

INFLUVAC SUBUNIT (indicated in adults and children from 6 months of age).

For prophylaxis of influenza, particularly indicated in:

1. Persons who are at high risk for influenza and its complications because of underlying medical conditions and who are receiving regular medical care for conditions such as

chronic pulmonary and cardiac diseases, chronic renal diseases, diabetes mellitus and similar metabolic disorders and individuals who are immunosuppressed;

2. Residents of old age homes, chronic care rehabilitation institutions;
3. Children on long-term aspirin therapy;
4. Medical and nursing staff responsible for the care of high risk cases;
5. Adults and children who are family contacts of high risk cases;
6. All persons over the age of 65; and
7. Any person wishing to protect themselves from the risk of contracting influenza, especially in industrial settings, where large scale absenteeism could cause significant economic losses.

4.2 Posology and method of administration

Posology

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

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

To be given by intramuscular or deep subcutaneous injection after allowing the vaccine to reach room temperature. Shake before use. Inspect visually prior to administration.

In the absence of compatibility studies, INFLUVAC SUBUNIT must not be mixed with other medicines.

Instructions for use:

- Disinfect the injection area and allow to dry completely.
- Remove the needle guard.
- Keep the syringe in an upright position and expel air by moving the plunger gently upward.
- The syringe is now ready for use.

For the administration of a 0,25 mL dose from a single dose 0,5 mL syringe (for paediatric use only):

- Push the front side of the plunger exactly to the edge of the mark so that half of the volume is eliminated; a volume of 0,25 mL of the vaccine remains in the syringe, suitable for administration.

4.3 Contraindications

Hypersensitivity to the active substances, to any of the excipients (see section 6.1) or to any component that may be present as traces such as eggs (ovalbumin, chicken proteins), formaldehyde, cetyltrimethylammonium bromide, polysorbate 80 and gentamycin.

Persons with febrile illnesses or acute infection should preferably be immunised after the symptoms have disappeared.

4.4 Special warnings and precautions for use

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

INFLUVAC SUBUNIT should under no circumstances be administered intravascularly.

As with other vaccines administered intramuscularly, INFLUVAC SUBUNIT should be given with caution to individuals with thrombocytopenia or any coagulation disorder since bleeding may occur following an intramuscular administration to these patients.

Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-

related reactions can occur following, or even before, any vaccination as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.

INFLUVAC SUBUNIT is not effective against all possible strains of influenza virus. INFLUVAC SUBUNIT is intended to provide protection against those strains of virus from which the vaccine is prepared and to closely related strains.

As with any vaccine, a protective immune response may not be elicited in all vaccinees.

Antibody response in patients with endogenous or iatrogenic immunosuppression may be insufficient.

Interference with serological testing (see section 4.5).

The vaccine may contain minimal amounts of gentamycin, polymyxin and neomycin. Use with caution in patients hypersensitive to these antibiotics (see section 4.3).

Adverse events may be aggravated after simultaneous administration of vaccines. Persons known to be sensitive to vaccination should, therefore, observe a waiting period of 3 weeks, unless the influenza season has already started.

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.

4.5 Interaction with other medicines and other forms of interaction

INFLUVAC SUBUNIT may be given at the same time as other vaccines. Immunisation should be carried out on separate limbs. It should be noted that the adverse reactions may be intensified. INFLUVAC SUBUNIT must not be mixed with other medicines.

The immunological response may be diminished if the patient is undergoing immunosuppressant treatment.

Following influenza vaccination, false-positive results in serology tests using the enzyme-linked-

immunosorbent assay (ELISA) method to detect antibodies against human immunodeficiency virus type 1 (HIV1), hepatitis C and especially human T-lymphotropic virus type 1 (HTLV1) have been observed. The Western Blot technique disproves the false-positive ELISA test results. The transient false-positive reactions could be due to the immunoglobulin M (IgM) response by the vaccine.

4.6 Fertility, pregnancy and lactation

Pregnancy

INFLUVAC SUBUNIT 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 influenza vaccine do not indicate any adverse fetal and maternal outcomes attributable to the vaccine.

Breastfeeding

INFLUVAC SUBUNIT may be used during breastfeeding.

Fertility

No fertility data is available.

4.7 Effects on ability to drive and use machines

INFLUVAC SUBUNIT has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

a. Summary of the safety profile

The most frequently reported adverse reactions following use of INFLUVAC SUBUNIT are local and/or systemic reactions such as injection site pain or fatigue and headache. These reactions usually disappeared spontaneously within 1-2 days after onset. Most of these adverse reactions are of mild to moderate intensity.

In rare cases, allergic reactions may evolve to shock, angioedema (see section 4.4).

b. Tabulated summary of adverse reactions

The safety of trivalent influenza vaccines is assessed in open label, uncontrolled clinical trials performed as an annual update requirement, including at least 50 adults aged 18 – 60 and at least 50 elderly subjects aged 61 years and older. Safety evaluation is performed during the first 3 days following vaccination.

The following undesirable effects have been observed during clinical trials with the following frequencies: very common (≥ 1/10); common (≥ 1/100, < 1/10); uncommon (≥ 1/1000, < 1/100); rare (≥ 1/10 000, < 1/1000); very rare (< 1/10 000), including isolated reports.

Organ class	**Very common (≥1/10)**	**Common (≥ 1/100, < 1/10)**	**Uncommon (≥ 1/1000, < 1/100)**	**Rare (≥ 1/10 000, < 1/1000)**	**Very rare (<1/10 000)**
Nervous system disorders		Headache*			
Skin and subcutaneous tissue disorders		Sweating*			
Musculoskeletal and connective tissue disorders		Myalgia, arthralgia*			
General disorders and administration site conditions		Fever, malaise, shivering, fatigue. Local reactions:			

		redness, swelling, pain, ecchymosis, induration*			

*These reactions usually disappear within 1-2 days without treatment.

From post-marketing surveillance additionally, the following adverse events have been reported. The frequencies are unknown:

Blood and lymphatic system disorders:

Transient thrombocytopenia, transient lymphadenopathy.

Immune system disorders:

Allergic reactions, in rare cases leading to shock, angioedema.

Nervous system disorders:

Neuralgia, paraesthesia, febrile convulsions, neurological disorders, such as encephalomyelitis, neuritis and Guillain Barré syndrome.

Vascular disorders:

Vasculitis associated in very rare cases with transient renal involvement.

Skin and subcutaneous tissue disorders:

Generalised skin reactions including pruritus, urticaria or non-specific rash.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. Abbott Laboratories South Africa Pharmacovigilance: pv.south-africa@abbott.com.

4.9 Overdose

Overdosage is unlikely to have any untoward effect.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological classification: A. 30.1 Antigens.

Pharmacotherapeutic group: Influenza vaccine, ATC Code: J07BB02.

Mechanism of action

Studies have shown that the purified haemagglutinin and neuraminidase antigens contained in INFLUVAC SUBUNIT produce a protective antibody level against influenza in a high percentage of vaccines. Seroprotection is generally obtained within 2 to 3 weeks.

The duration of post-vaccinal immunity to homologous strains or to strains closely related to the vaccine strains varies but is usually 6 – 12 months. INFLUVAC SUBUNIT inactivated influenza vaccine will only offer protection against the strains of the virus which are mentioned on the label.

5.2 Pharmacokinetic properties

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium chloride dihydrate

Disodium phosphate dihydrate

Magnesium chloride hexahydrate

Potassium chloride

Potassium dihydrogen phosphate

Sodium chloride

Water for injection.

6.2 Incompatibilities

In the absence of compatibility studies, INFLUVAC SUBUNIT must not be mixed with other medicines.

6.3 Shelf life

1 year.

6.4 Special precautions for storage

Store at 2 to 8 °C in a refrigerator (avoid freezing). Store in the original package in order to protect from light. Shake well before use; a slight turbidity may occur.

6.5 Nature and contents of container

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.

6.6 Special precautions for disposal and other handling

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

Shake before use. Inspect visually prior to administration.

Any unused product or waste material should be disposed of in accordance with local requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Abbott Laboratories S.A. (Pty) Ltd

Abbott Place, 219 Golf Club Terrace

Constantia Kloof, 1709

South Africa

8. REGISTRATION NUMBER

T/30.1/581

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

27 August 1993

10. DATE OF REVISION OF THIS TEXT

12 March 2026

NAME AND ADDRESS OF MANUFACTURER

Abbott Biologicals B.V

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