AUSTRALIAN PRODUCT INFORMATION

INFLUVAC®

(influenza virus haemagglutinin) suspension for injection

1 NAME OF THE MEDICINE

Trivalent Influenza Vaccine, surface antigen, inactivated (influenza virus haemagglutinin)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

INFLUVAC is a purified, inactivated influenza vaccine (surface antigen), containing the following three influenza strains recommended for the 2027 influenza season:

- A/Missouri/11/2025 (H1N1)pdm09-like virus
  (A/Missouri/11/2025, IVR-279)

- A/Darwin/1454/2025 (H3N2)-like virus
  (A/Michigan/105/2025, SAN-049A)

- B/Tokyo/EIS13-175/2025 (B/Victoria lineage)-like virus
  (B/Tokyo/EIS13-175/2025, wild type)

Each 0.5 mL dose contains 15 micrograms haemagglutinin per each of the above mentioned viral strains, for a combined total amount of 45 micrograms. Each strain has been propagated in fertilised hens' eggs from healthy chickens.

The type and amount of viral antigens in INFLUVAC conform to the requirements of the Australian Influenza Vaccine Committee (AIVC) and the New Zealand Ministry of Health for the 2027 southern hemisphere influenza season.

For the full list of excipients, see Section 6.1 LIST OF EXCIPIENTS.

3 PHARMACEUTICAL FORM

INFLUVAC is a clear colourless liquid for injection in pre-filled syringes (glass, type I).

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

For the prevention of influenza caused by influenza virus, types A and B.

For full details regarding recommendations for influenza vaccination, please refer to the relevant National Immunisation Guidelines.

INFLUVAC is indicated in adults and children from 6 months of age and older.

4.2 DOSE AND METHOD OF ADMINISTRATION

One dose is sufficient for persons previously exposed to viruses of similar antigenic composition to the strain(s) present in the vaccine. In those with some impairment of immune mechanisms, two doses separated by an interval of at least four weeks are recommended.

Adults and children 6 months of age and older: 0.5 mL

For children less than 9 years of age who have not previously been vaccinated, a second dose of 0.5 mL should be given after an interval of at least four weeks.

The Australian Immunisation Handbook recommends that preterm infants should receive influenza vaccine every year, starting from 6 months of age and have a second dose at least 4 weeks later if receiving influenza vaccine for the first time.

Children less than 6 months of age: the safety and efficacy of INFLUVAC has not been established.

INFLUVAC should be administered in autumn before the beginning of the influenza season or as required by the epidemiological situation. Vaccination should be repeated every year.

Administration

INFLUVAC should be administered by intramuscular or deep subcutaneous injection, whereas the intramuscular route is preferred.

INFLUVAC should not be administered intravenously.

INFLUVAC should not be mixed with other injection fluids.

The syringe is for use in a single patient on one occasion only, any remaining residue should be discarded.

Instructions for use/handling

INFLUVAC should be allowed to reach room temperature, shaken well and inspected visually before use.

Please refer to the relevant National Immunisation Guidelines for full details on preparations and vaccine administration.

4.3 CONTRAINDICATIONS

Hypersensitivity to the active substances, or to any component of the vaccine, except egg proteins (see Section 2 – QUALITATIVE AND QUANTITATIVE COMPOSITION and Section 6.1 – LIST OF EXCIPIENTS). Refer to Section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE for vaccination in individuals with a known egg allergy.

Anaphylaxis following a previous dose of any influenza vaccine.

Refer to the relevant National Immunisation Guidelines for full details on contraindications and precautions.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

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

Immunisation should be postponed in patients with an acute febrile illness.

The presence of a minor illness with or without fever should not contraindicate the use of INFLUVAC.

INFLUVAC is required to contain no more than 1 µg ovalbumin per dose. People with egg allergy, including a history of anaphylaxis, can be safely vaccinated unless they have reported a serious adverse reaction to influenza vaccines. Egg allergy does not increase the risk of anaphylaxis but anaphylaxis to other components may occur. Refer to the current Australian Immunisation Handbook for guidance on the use of influenza vaccines in individuals with egg allergy.

INFLUVAC should under no circumstances be administered intravascularly.

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

Patients with impaired immune responsiveness, whether due to the use of immunosuppressive therapy, a genetic defect, human immunodeficiency virus (HIV) infection, or other causes, may have a reduced antibody response in active immunisation procedures.

Patients with a history of Guillain-Barre syndrome (GBS) with an onset related in time to influenza vaccination may be at increased risk of again developing GBS if given influenza vaccine. While this risk should be weighed against the benefits to the individual patient of influenza vaccination, it would seem prudent to avoid subsequent influenza vaccination in this group. Because patients with a history of GBS have an increased likelihood of again developing the syndrome, the chance of them coincidentally developing the syndrome following influenza vaccination may be higher than in individuals with no history of GBS.

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 is not effective against all possible strains of influenza virus. INFLUVAC 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.

This medicine contains sodium, less than 1 mmol (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’.

Paediatric Use

Use in Children younger than 6 months

The safety and efficacy of INFLUVAC in children younger than 6 months have not been established. No data are available.

Effects on Laboratory Tests

Following influenza vaccination, false positive results in serology tests using the ELISA method to detect antibodies against HIV1, Hepatitis C and especially HTLV1 have been observed. The Western Blot technique disproves the results. The transient false positive reactions could be due to the IgM response by the vaccine.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Influenza vaccine can impair the metabolism of warfarin, theophylline, phenytoin, phenobarbitone and carbamazepine by the hepatic P450 system. Results from studies have been variable in degree of interaction and time after vaccination for the interaction to take effect. The interaction may be idiosyncratic. Patients taking warfarin, theophylline, phenytoin, phenobarbitone, or carbamazepine should be advised of the possibility of an interaction and told to look out for signs of elevated levels of medication.

INFLUVAC should not be mixed with other vaccines in the same syringe.

No interaction studies have been performed. If INFLUVAC is 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.

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

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on Fertility

No animal or human fertility data are available.

Use in Pregnancy

Category B2.

Inactivated influenza 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 influenza vaccine do not indicate any adverse fetal or maternal outcomes attributable to the vaccine.

Health authorities recommend vaccination for all pregnant women at any stage of pregnancy, particularly those who will be in the second or third trimester during the influenza season.

Use in Lactation

INFLUVAC may be used during lactation.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

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

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Clinical Trial Experience

a) Summary of the safety profile

In two clinical studies, healthy adults 18 years of age and older and healthy children 3 to 17 years of age were administered INFLUVAC TETRA (1535 adults and 402 children) or trivalent influenza vaccine, INFLUVAC (442 adults and 798 children). Similar rates of solicited adverse reactions were observed in recipients of INFLUVAC TETRA and trivalent influenza vaccine INFLUVAC. In a third clinical study, 1005 children aged 6 to 35 months were administered INFLUVAC TETRA and compared to 995 children receiving a non-influenza vaccine. The rates of solicited systemic adverse reactions were similar in both vaccine groups, whereas the rates of solicited local adverse reactions were lower in recipients of INFLUVAC TETRA.

The most frequently reported local adverse reaction after vaccination with INFLUVAC TETRA in all age groups was pain at injection site (16.3% in adults 18 years of age and older, 59.0% in children aged 3 to 17 years, and 22.6% in children aged 6 to 35 months).

In adults 18 years of age and above, the most frequently reported general adverse reactions after vaccination were fatigue (11.2%) and headache (10.3%).

In children aged 6 to 17 years, the most frequently reported general adverse reactions after vaccination were headache (24.0%) and fatigue (23.6%).

In children aged 6 to 35 months and 3 to 5 years, the most frequently reported general adverse reaction after vaccination was irritability (30.2% and 21.0% respectively).

b) Tabulated list of adverse reactions

Table 1: Percentage of Solicited Injection-Site Reactions and Systemic Adverse Events in Adults After Vaccination with INFLUVAC TETRA (Safety Analysis Set) versus Comparator

	Adults 18 years of age and older (Safety sample)		**Adults 61 years of age and older (Safety sample)**	
	INFLUVAC TETRA[c] N=768	**TIV[a,b] N=222 (Pooled data: TIV-1: B Victoria N=110, TIV-2: B Yamagata N=112)**	**INFLUVAC TETRAc N=767**	**TIV[a,b] N=219 (Pooled data: TIV-1: B Victoria N=111, TIV-2: B Yamagata N=108)**
Injection-site reactions				
Pain	24.9%	18.5%	7.6%	5.9%
Redness	2.6%	4.1%	3.5%	0.9%
Swelling	5.2%	6.3%	4.8%	3.2%
Ecchymosis	2.7%	3.2%	2.8%	1.8%
Induration	5.0%	6.8%	3.9%	2.3%
Systemic reactions				
Headache	12.4%	13.1%	8.1%	7.3%
Myalgia	7.3%	5.9%	7.5%	5.0%
Arthralgia	4.6%	3.2%	5.8%	2.3%
Malaise	5.9%	7.7%	6.4%	4.6%
Shivering	3.1%	2.7%	4.7%	2.7%
Fatigue	11.9%	12.6%	10.6%	6.8%
Sweating	4.4%	5.0%	5.9%	4.1%
Fever	0.1%	0%	0.9%	0.9%

N is the number of subjects in the safety analysis set

a 2014-2015 INFLUVAC TIV containing A/California/7/2009 (H1N1)pdm09-like strain (A/California/7/2009, X-181), A/Texas/50/2012 (H3N2)-like strain (A/Texas/50/2012, X-223A) , B/Brisbane/60/2008 (wild type) ($TIV_{(Vic)}$) (market formulation)

b 2014-2015 INFLUVAC TIV containing A/California/7/2009 (H1N1)pdm09-like strain (A/California/7/2009, X 181), A/Texas/50/2012 (H3N2)-like strain (A/Texas/50/2012, X 223A) , B/Massachusetts/2/2012-like strain (B/Massachusetts/2/2012, BX-51B) TIV($_{Yam}$) non-licensed formulation

c 2014-2015 INFLUVAC TETRA A/California/7/2009 (H1N1)pdm09-like strain (A/California/7/2009, X 181), A/Texas/50/2012 (H3N2)-like strain (A/Texas/50/2012, X 223A), B/Massachusetts/2/2012-like strain (B/Massachusetts/2/2012, BX-51B) TIV($_{Yam}$)) , B/Brisbane/60/2008 (wild type) ($TIV_{(Vic)}$) non-licensed formulation

These reactions usually disappear within 1-3 days without treatment.

Table 2: Percentage of Solicited Injection-Site Reactions and Systemic Adverse Events in Children 3-17 years After Vaccination with INFLUVAC TETRA (Safety Analysis Set) versus Comparator

Age group	Solicited Reaction	INFLUVAC TETRA[c] N=402	TIV[a,b] N=798 (Pooled data: TIV-1: B Victoria N=404, TIV-2: B Yamagata N=394)
Injection-site reactions			
3-17 years	Pain	59.0%	52.5%
	Redness	19.4%	16.6%
	Swelling	13.4%	10.7%
	Ecchymosis	6.5%	4.5%
	Induration	11.4%	10.1%
Systemic reactions			
3-17 years	Fever	4.2%	2.6%
	Sweating	4.2%	3.9%
6-17 years	Headache	24.0%	20.9%
	Fatigue	23.6%	22.1%
	Gastro-intestinal symptoms	14.8%	10.0%
	Myalgia	14.8%	15.3%
	Arthralgia	6.1%	4.9%
	Malaise	14.8%	12.3%
	Shivering	4.4%	3.5%
3-5 years	Irritability	21.0%	17.8%
	Drowsiness	15.9%	12.7%
	Diarrhea/Vomiting	6.8%	7.3%
	Loss of appetite	13.1%	11.1%

N is the number of subjects in the safety analysis set

[a] 2016-2017 INFLUVAC TIV with alternative B strain Tetra containing A/California/7/2009 (H1N1)pdm09-like virus, A/Hong Kong/4801/2014 (H3N2)-like virus, and B/Phuket/3073/2013-like virus

[b] 2016-2017 marketed INFLUVAC TIV containing A/California/7/2009 (H1N1)pdm09-like virus, A/Hong Kong/4801/2014 (H3N2)-like virus, and B/Brisbane/60/2008-like virus

[c] 2016-2017 INFLUVAC TETRA containing A/California/7/2009 (H1N1)pdm09-like virus, A/Hong Kong/4801/2014 (H3N2)-like virus, B/Brisbane/60/2008-like virus and B/Phuket/3073/2013-like virus

Note: *Reactogenicity data of the two trivalent formulations pooled; RR = Relative Risk QIV vs TIV.

Note: Two sided 95 % CI. For the adjusted RR this is obtained based on the Mantel-Haenszel method.

Note: ** Adjusted for center and age/priming (9-17 years, 3-8 years primed and 3-8 years unprimed)

These reactions usually disappear within 1-3 days without treatment.

Table 3: Percentage of Solicited Injection-Site Reactions and Systemic Adverse Events in Children aged 6 to 35 months after Vaccination with INFLUVAC TETRA (Safety Analysis Set) versus Comparator

	Solicited Reaction	INFLUVAC TETRA N=1005	NIV* N=995
Injection-site reactions			
	Pain	22.6%	27.0%
	Redness	11.6%	19.6%
	Swelling	4.3%	7.2%
	Ecchymosis	4.0%	4.8%
	Induration	4.4%	10.4%
Systemic reactions			
	Fever	19.3%	18.1%
	Sweating	12.4%	11.5%
	Irritability	30.2%	33.6%
	Drowsiness	17.5%	17.3%
	Diarrhea/Vomiting	19.8%	18.0%
	Loss of appetite	19.3%	21.9%

N is the number of subjects in the safety analysis set
* NIV non-influenza vaccine (for more details, see **Section 5.1 Pharmacodynamic Properties – Clinical Trials**)

These reactions usually disappear within 1-3 days without treatment.

Adverse Reactions Reported from Post-Marketing Surveillance

The following adverse reactions have been observed for INFLUVAC and/or INFLUVAC TETRA during post-marketing surveillance[1].

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 Barre 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.

[1]Three of the influenza strains contained in INFLUVAC are included in INFLUVAC TETRA.

Reporting Suspected Adverse Effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Given the nature of the product and mode of administration the probability of over dosage is negligible.

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of Action

The vaccine stimulates production of antibodies with a specific capacity against influenza. Protection is only against those strains of the virus from which the vaccine is prepared or closely related strains.

Seroprotection is obtained within 2-3 weeks. The duration of post-vaccination immunity varies between 6-12 months.

5.2 PHARMACOKINETIC PROPERTIES

Not applicable.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No genotoxicity studies have been conducted with INFLUVAC.

Carcinogenicity

No carcinogenicity studies have been conducted with INFLUVAC.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Each 0.5 mL dose contains 0.10 mg potassium chloride, 0.10 mg monobasic potassium phosphate, 0.67 mg dibasic sodium phosphate dihydrate, 4.0 mg sodium chloride, 0.067 mg calcium chloride dihydrate, 0.05 mg magnesium chloride hexahydrate and q.s. to 0.5 mL water for injections.

INFLUVAC antigens have been produced from eggs and are inactivated by formaldehyde treatment. Each 0.5 mL may also contain not more than 100 ng ovalbumin, 0.01 mg formaldehyde, 0.015 mg cetrimonium bromide, 1 mg sodium citrate, 0.2 mg sucrose, 1 ng gentamicin sulfate, trace amounts of chicken proteins, traces of tylosine tartrate, hydrocortisone and polysorbate 80, which are used during the manufacturing process.

6.2 INCOMPATIBILITIES

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

See section 4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Keep out of the sight and reach of children.

Store between 2 and 8 degrees Celsius. Refrigerate, do not freeze. Store in the original package in order to protect from light.

6.5 NATURE AND CONTENTS OF CONTAINER

Single-dose 0.5 mL pre-filled glass syringe, 1's and 10's.

Some strengths, pack sizes and/or pack types may not be marketed.

Australian Register of Therapeutic Goods (ARTG)

AUST R 432790 – INFLUVAC influenza virus haemagglutinin 0.5mL vaccine prefilled syringe with 16 mm needle

AUST R 432810 – INFLUVAC influenza virus haemagglutinin 0.5mL vaccine prefilled syringe with 25 mm needle

AUST R 432811 – INFLUVAC influenza virus haemagglutinin 0.5mL vaccine prefilled syringe without needle

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 PHYSICOCHEMICAL PROPERTIES

Not applicable

7 MEDICINE SCHEDULE (POISONS STANDARD)

S4 (Prescription Only Medicine)

8 SPONSOR

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9 DATE OF FIRST APPROVAL

21/01/2025

10 DATE OF REVISION

09/11/2026

Summary Table of Changes

Section Changed	Summary of New Information
2	Annual strain update for southern hemisphere 2027.

INFLUVAC® is a Viatris company trade mark

INFLUVAC_pi\Nov26/00 (CCDS 05-Sep-2025)