**AUSTRALIAN PRODUCT INFORMATION**

# INFLUVAC® TETRA

*(influenza virus haemagglutinin) suspension for Injection*

## 1 NAME OF THE MEDICINE

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

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

INFLUVAC TETRA is a purified, inactivated influenza vaccine (surface antigen), containing the following four influenza strains recommended for the 2026 influenza season:

- A/Missouri/11/2025 (H1N1)pdm09-like virus
  (A/Switzerland/6849/2025, IVR-278
- A/Singapore/GP20238/2024 (H3N2)-like virus
  (A/Singapore/GP20238/2024, IVR-277
- B/Austria/1359417/2021-like virus (B/Victoria lineage)
  (B/Austria/1359417/2021, BVR-26)
- B/Phuket/3073/2013-like virus (B/Yamagata lineage)
  (B/Phuket/3073/2013, 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 60 micrograms. Each strain has been propagated in fertilised hens' eggs from healthy chickens.

The type and amount of viral antigens in INFLUVAC TETRA conform to the requirements of the Australian Influenza Vaccine Committee (AIVC) for the 2026 southern hemisphere influenza season.

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

## 3 PHARMACEUTICAL FORM

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

### 4.2 DOSE AND METHOD OF ADMINISTRATION

**Adults and children 6 months of age and older**: 0.5 mL dose.

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 4 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. Clinical trial data for

INFLUVAC TETRA from study INFQ3003 were from infants aged 6-35 months (pre-term status is not known).

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

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

INFLUVAC TETRA should not be administered intravenously.

INFLUVAC TETRA should not be mixed with other injection fluids.

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

### Instructions for use/handling
INFLUVAC TETRA should be 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 Sections 2 QUALITATIVE AND QUANTITATIVE COMPOSITION & 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.

Immunisation should be postponed in patients with febrile illness or acute infection.

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 an anaphylactic event following the administration of the vaccine.

INFLUVAC TETRA 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 TETRA should under no circumstances be administered intravascularly.

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

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 TETRA is not effective against all possible strains of influenza virus. INFLUVAC TETRA 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 subheading 'Effects on laboratory tests' below.

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'.

### Use in the Elderly

The safety and immunogenicity of INFLUVAC TETRA was evaluated in adults ≥ 65 years in INFQ3001 (See Section 4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)). Overall serological responses in elderly subjects were lower than those in younger adult subjects.

### Paediatric Use

The safety and efficacy of INFLUVAC TETRA in children under 6 months of age have not been established.

### 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 false-positive ELISA test 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

No interaction studies have been performed. If INFLUVAC TETRA 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

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 TETRA may be used during lactation.

## 4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

INFLUVAC TETRA has no or negligible influence on the ability to drive and use of 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 TETRA[c] 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 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

[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 (Australia).

## 4.9 OVERDOSE

Given the nature of the product and mode of administration the probability of overdosage 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

INFLUVAC TETRA provides active immunisation against four influenza virus strains: An A/(H1N1) strain, an A/(H3N2) strain, a B/Victoria strain and a B/Yamagata strain. INFLUVAC TETRA, manufactured according to the same process as trivalent influenza vaccine INFLUVAC, induces humoral antibodies against the haemagglutinins. These antibodies neutralise influenza viruses with matching antigens which has entered the body during infection.

Specific levels of haemagglutination-inhibition (HI) antibody titer post-vaccination with inactivated influenza virus vaccines have not been correlated with protection from influenza illness but the HI antibody titers have been used as a measure of vaccine activity.

Seroprotection is obtained within 2-3 weeks. The duration of post-vaccination immunity to homologous strains or to strains closely related to the vaccine strains varies but is usually between 6-12 months.

### Clinical Trials

***Vaccine efficacy of INFLUVAC TETRA:***

Study INFQ3003 was a Phase III, randomized, observer-blind, non-influenza vaccine comparator-controlled, multicenter, multi-country (Europe and Asia) in subjects aged 6 to 35 months to demonstrate the absolute vaccine efficacy of quadrivalent influenza vaccine (QIV) in the prevention of symptomatic influenza infection due to any circulating seasonal influenza strain and of antigenically-matching influenza strains compared with non-influenza vaccines (NIVs).

The study was stratified by the age groups 6-11, 12-18, 19-24, and 25-35 months, with a minimum enrolment of 250 subjects per age group overall. The study included 2 cohorts (Cohort 1 and Cohort 2) and was conducted over 3 influenza seasons (Northern Hemisphere 2017/2018 and 2018/2019, and Southern Hemisphere 2019). QIV vaccination consisted of 2 doses 4 weeks apart, and containing the viral strains recommended for the NH season 2017/2018 for Cohort 1, and for NH season 2018/2019 or SH season 2019 for Cohort 2. The revaccination subset from Cohort 1 received NH 2018/2019 vaccine in Year 2. A revaccination with QIV was conducted in the second influenza season for 334 subjects of Cohort 1 vaccinated with QIV in the first year, to assess the persistence of the immune response to QIV and to assess the immunogenicity and safety following revaccination.

The comparator non-influenza vaccine (NIV) was given in the same schedule. Subjects received pneumococcal conjugate vaccine or meningococcal group C conjugate vaccine if 6-11 months of age, or either hepatitis A, tick-borne encephalitis, or varicella vaccine if 12-35 months of age, at the time of the first vaccination on Day 1.

Of the subjects who received both vaccinations, 59 subjects in the INFLUVAC TETRA group and 117 subjects in the non-influenza vaccine group had at least 1 real-time polymerase chain reaction (RT PCR) confirmed

circulating seasonal influenza A and/or B infection during the influenza surveillance period of the applicable cohort resulting in a hazard ratio (HR) of 0.46 (95%CI: 0.34 to 0.63). Absolute influenza vaccine efficacy (VE) of INFLUVAC TETRA was VE=1-HR, i.e. 0.54 (95%CI 0.37 to 0.66).

Further, 19 subjects in the INFLUVAC TETRA group and 56 subjects in the non-influenza vaccine group had at least 1 RT PCR confirmed antigenically matching influenza strain during the influenza surveillance period of the applicable cohort resulting in a HR of 0.32 (95%CI: 0.19 to 0.55). Absolute influenza vaccine efficacy of INFLUVAC TETRA was VE=1-HR, i.e. 0.68 (95% CI: 0.45 to 0.81).

**Table 4 Absolute Vaccine Efficacy of INFLUVAC TETRA in the Prevention of Symptomatic Influenza Infection due to Any Seasonal Influenza Strain and Antigenically Matching Vaccine strains – Full Analysis Sample Since 28 Days Post-Second Vaccination**

| **Children 6-35 months** | **INFLUVAC TETRA (N=1005)** | **Non-influenza vaccine (N=995)** | **INFLUVAC TETRA / NIV** | | **INFLUVAC TETRA Efficacy** | **95%CI** |
|---|---|---|---|---|---|---|
| | | | **Hazard Ratio** | **95%CI** | | |
| Number of Subjects Who Received both First and Second Vaccination | 991 | 981 | | | | |
| **Any Seasonal Influenza Strains** | | | | | | |
| Number of Subjects With PCR-Confirmed influenza A/B | 59 | 117 | | | | |
| Number of Censored Observations | 923 | 852 | | | | |
| | | | 0.46 | 0.34 – 0.63 | 0.54 | 0.37 – 0.66 |
| **Antigenically Matching Vaccine strains** | | | | | | |
| Number of Subjects With PCR-Confirmed influenza A/B | 19 | 56 | | | | |
| Number of Censored Observations | 963 | 913 | | | | |
| | | | 0.32 | 0.19 – 0.55 | 0.68 | 0.45 – 0.81 |

N= number of patients (full analysis sample)
NIV = Non-influenza vaccine; CI = confidence interval

The absolute efficacy of INFLUVAC TETRA in the prevention of symptomatic influenza infection compared with a non-influenza vaccine in children aged 6 to 35 months was demonstrated with an overall efficacy of 54% for any strain and 68% for the strains contained in the vaccine, which persisted over the 6-month surveillance period.

***Immunogenicity of INFLUVAC TETRA:***

Clinical studies performed in adults 18 years of age and older (INFQ3001) and children 3 to 17 years of age (INFQ3002) assessed the safety and immunogenicity of quadrivalent INFLUVAC TETRA and its non-inferiority to trivalent influenza vaccine INFLUVAC. The post-vaccination immunogenicity was assessed using HI Geometric mean antibody titer (GMT). The third study in children 6 months to 35 months (INFQ3003) compared the immunogenicity of quadrivalent INFLUVAC TETRA to a non-influenza vaccine.

Studies INFQ3001 and INFQ3002 found that the immune response elicited by INFLUVAC TETRA against the three viral strains in common was non-inferior to trivalent INFLUVAC. Additionally, INFLUVAC TETRA elicited a superior immune response against the additional B strain included in INFLUVAC TETRA compared to trivalent INFLUVAC.

Adults 18 years of age and older:

In clinical study INFQ3001, 1535 adults 18 years of age and older received a single dose of INFLUVAC TETRA and 442 subjects received a single dose of trivalent INFLUVAC:

**Table 5: Post-vaccination GMT**

| **Adults 18 years of age and older** | **INFLUVAC TETRA N=1533** | **INFLUVAC[1] N=440** |
|---|---|---|
| | **GMT (95% confidence interval)** | |
| **A/H1N1** | 186.2 (173.3;200.0) | 221.6 (194.1;253.1) |
| **A/H3N2** | 392.8 (368.7;418.4) | 411.9 (364.3;465.8) |
| **B (Yamagata)[2]** | 101.9 (94.8;109.7) | 86.6 (71.5;105.0) |
| **B (Victoria)[3]** | 153.1 (142.3;164.7) | 140.7 (114.5;172.8) |

[1]containing A/H1N1, A/H3N2 and B (Yamagata lineage) (N = 220) or B (Victoria lineage) (N = 220)
[2]recommended B strain by WHO for the season 2014-2015 NH for trivalent vaccines
[3]additional recommended B strain by WHO for season 2014-2015 NH for quadrivalent vaccines
N = number of patients (full analysis sample)

Children 3 to 17 years of age:

In clinical study INFQ3002, 402 children of 3 to 17 years of age received one or two doses of INFLUVAC TETRA and 798 children received one or two doses of trivalent INFLUVAC based on their influenza vaccination history (primed or naïve):

**Table 6: Post-vaccination GMT**

| **Children 3-17 years** | **INFLUVAC TETRA N=396** | **INFLUVAC[1] N=788** |
|---|---|---|
| | **GMT (95% confidence interval)** | |
| **A/H1N1** | 546.2 (487.1; 612.6) | 619.4 (569.2; 673.9) |
| **A/H3N2** | 1161.5 (1035.8; 1302.5) | 1186.7 (1088.9; 1293.3) |
| **B (Yamagata)[2]** | 280.8 (246.2; 320.1) | 269.0 (232.8; 310,7) |
| **B (Victoria)[3]** | 306.7 (266.0; 353.6) | 361.4 (311.0; 420.0) |

[1]containing A/H1N1, A/H3N2 and B (Yamagata lineage) (N=389) or B (Victoria lineage) (N=399)
[2]recommended B strain by WHO for the season 2016-2017 NH for trivalent vaccines
[3]additional recommended B strain by WHO for season 2016-2017 NH for quadrivalent vaccines
N= number of patients (full analysis sample)

Children 6-35 months of age:

In clinical study INFQ3003, 1005 children of 6-35 months of age were to receive two doses of INFLUVAC TETRA and 995 children were to receive two doses of a non-influenza vaccine:

**Table 7: Post-vaccination GMT**

| **Children 6-35 months Post vaccination GMT (GSD)** | | **INFLUVAC TETRA** | **Non-influenza vaccine** |
|---|---|---|---|
| **Cohort 1 NH[1]** | | **(N=348)** | **(N=343)** |
| | A/H1N1 | 71.1 (4.4) | 12.0 (4.1) |
| | A/H3N2 | 341.4 (6.7) | 12.9 (5.7) |
| | B (Yamagata) | 10.8 (3.1) | 5.6 (1.7) |
| | B (Victoria) | 11.1 (4.0) | 5.3 (1.5) |
| **Cohort 2 NH[2]** | | **(N=359)** | **(N=346)** |
| | A/H1N1 | 84.2 (4.5) | 11.9 (4.5) |
| | A/H3N2 | 156.0 (6.0) | 9.2 (4.0) |
| | B (Yamagata) | 20.3 (4.0) | 5.4 (1.4) |
| | B (Victoria) | 27.0 (3.9) | 5.0 (1.1) |
| **Cohort 2 SH[3]** | | **(N=225)** | **(N=221)** |
| | A/H1N1 | 116.2 (8.4) | 17.5 (5.7) |
| | A/H3N2 | 554.2 (9.0) | 12.0 (5.4) |
| | B (Yamagata) | 8.9 (3.7) | 5.0 (1.0) |
| | B (Victoria) | 24.9 (5.9) | 5.0 (1.2) |

N = number of patients (immunogenicity sample)
Note: GMT = Geometric Mean Titer; GSD = Geometric Standard Deviation.
[1] Season Northern Hemisphere 2017-2018: A/Michigan/45/2015 (H1N1)pdm09-like virus; A/Hong Kong/4801/2014 (H3N2)-like virus; B/Brisbane/60/2008-like virus*; B/Phuket/3073/2013-like virus**
[2] Season Northern Hemisphere 2018-2019: A/Michigan/45/2015 (H1N1)pdm09-like virus; A/Singapore/INFIMH-16-0019/2016 (H3N2)-like virus; B/Colorado/06/2017-like virus*; B/Phuket/3073/2013-like virus**
[3] Season Southern Hemisphere 2019: A/Michigan/45/2015 (H1N1)pdm09-like virus; A/Switzerland/8060/2017 (H3N2)-like virus; B/Colorado/06/2017-like virus*; B/Phuket/3073/2013-like virus**
* B/Victoria lineage; ** B/Yamagata lineage

## 5.2 PHARMACOKINETIC PROPERTIES

Not applicable

## 5.3 PRECLINICAL SAFETY DATA

### Genotoxicity

No genotoxicity studies have been conducted with INFLUVAC TETRA.

### Carcinogenicity

No carcinogenicity studies have been conducted with INFLUVAC TETRA.

# 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 TETRA 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, 0.02 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°C and 8°C. 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, available in packs of 1 or 10.

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

**Australian Register of Therapeutic Goods (ARTG)**

AUST R 292237 – INFLUVAC TETRA influenza virus haemagglutinin 0.5mL vaccine prefilled syringe with 16 mm needle

AUST R 292238 – INFLUVAC TETRA influenza virus haemagglutinin 0.5mL vaccine prefilled syringe with 25 mm needle

AUST R 281035 – INFLUVAC TETRA influenza virus haemagglutinin 0.5mL vaccine prefilled syringe without needle

## 6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

Any unused medicine or waste material should be disposed of immediately.

## 6.7 PHYSICOCHEMICAL PROPERTIES

Not applicable

# 7 MEDICINE SCHEDULE (POISONS STANDARD)

S4 (Prescription Only Medicine)

# 8 SPONSOR

**Viatris Pty Ltd**

Level 1, 30 The Bond

30 – 34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

# 9 DATE OF FIRST APPROVAL

02/11/2017

# 10 DATE OF REVISION

13/11/2025

**Summary Table of Changes**

| Section Changed | Summary of New Information |
|---|---|
| **All** | Minor editorial changes. |
| **2** | Annual strain update for 2026. |



**INFLUVAC TETRA_pi\Nov25/00**