NEW ZEALAND DATA SHEET

INFLUVAC® TETRA

1. Product Name

Influvac Tetra, 60 microgram haemagglutinin per 0.5 mL, Suspension for injection.

2. Qualitative and Quantitative Composition

Influvac Tetra is a purified, inactivated influenza vaccine (surface antigen), containing the following four influenza strains recommended for the 2025 influenza season:

- A/Victoria/4897/2022 (H1N1)pdm09-like strain
  (A/Victoria/4897/2022, IVR-238)
- A/Croatia/10136RV/2023 (H3N2)-like strain
  (A/Croatia/10136RV/2023, X-425A)
- B/Austria/1359417/2021-like strain (B/Victoria lineage)
  (B/Austria/1359417/2021, BVR-26)
- B/Phuket/3073/2013-like strain (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 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) and the New Zealand Ministry of Health for the 2025 southern hemisphere influenza season.

For a full list of excipients, see section 6.1.

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 nanograms ovalbumin, 0.01 mg formaldehyde, 0.02 mg cetrimonium bromide, 1 mg sodium citrate, 0.2 mg sucrose, 1 nanograms gentamicin sulfate, traces of tylosine tartrate, hydrocortisone and polysorbate 80 which are used during the manufacturing process.

3. Pharmaceutical Form

Influvac Tetra is a clear colourless liquid for injection in pre-filled syringes.

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

Dose

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 4 weeks.

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.

Method of 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 and 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 preparation and vaccine administration.

4.3 Contraindications

Hypersensitivity to the active substances, or to any component of the vaccine, except egg proteins (see sections 2 and 6.1). Refer to section 4.4 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.

Please 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 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 section 4.5.

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. Overall serological responses in elderly subjects were lower than those in younger adult subjects.

4.5 Interaction with other medicines and other forms of interaction

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.

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.

4.6 Fertility, pregnancy and lactation

Pregnancy

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 foetal 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.

Lactation

Influvac Tetra may be used during lactation.

Fertility

No animal or human fertility data are available.

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 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 months to 3 years 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 months to 3 years).

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

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.

b) Tabulated list of adverse reactions

The following undesirable effects have been observed during the clinical trials with Influvac Tetra with the following frequencies:

very common (≥ 1/10); common (≥ 1/100, <1/10); uncommon (≥ 1/1,000, <1/100); not known (cannot be estimated from the available data.

Adults and elderly

Organ class	**Very common ≥ 1/10**	**Common ≥ 1/100, <1/10**	**Uncommon ≥ 1/1,000, <1/100**	**Not known[a] (cannot be estimated from the available data)**
Blood and lymphatic system				Transient thrombocytopenia,

				transient lymphadenopathy
Immune system disorders				Allergic reactions, in rare cases leading to shock, angioedema
Nervous system disorders	Headache[b]			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		Sweating		Generalised skin reactions including pruritus, urticaria or non-specific rash
Musculoskeletal and connective tissue disorders		Myalgia, arthralgia		
General disorders and administration site conditions	Fatigue Local reaction: pain	Malaise, shivering, Local reactions: redness, swelling, ecchymosis, induration	Fever	

[a] Because these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to drug exposure
[b] In elderly adults (≥ 61 years) reported as common

Paediatric population

Children (3 to 17 years of age) adverse reactions reported with Influvac Tetra			
Organ class	**Very common** **≥ 1/10**	**Common** **≥ 1/100, <1/10**	**Not known**[a] **(cannot be estimated from the available data)**
Blood and lymphatic system			Transient thrombocytopenia, transient lymphadenopathy
Immune system disorders			Allergic reactions, in rare cases leading to shock, angioedema

Nervous system disorders	Headache[d] Drowsiness[b]		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		Sweating[c]	Generalised skin reactions including pruritus, urticaria or non-specific rash
Metabolism and nutrition disorders	Appetite loss[b]		
Gastrointestinal disorders	Gastrointestinal symptoms[d]	Diarrhoea[b], vomiting[b]	
Psychiatric disorders	Irritability[b]		
Musculoskeletal and connective tissue disorders	Myalgia[d]	Arthralgia[d]	
General disorders and administration site conditions	Fatigue[d], malaise[d] Local reactions: pain[c], redness[c], swelling[c], induration[c]	Fever[c], shivering[d] Local reaction: ecchymosis[c]	

[a] Because these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to drug exposure
[b] Reported as a solicited symptom in children 3 years to 5 years of age
[c] Reported as a solicited symptom in children 3 years to 17 years of age
[d] Reported as a solicited symptom in children 6 years to 17 years of age

Children (6 to 35 months of age) adverse reactions reported with Influvac Tetra			
Organ class	**Very common** **≥ 1/10**	**Common** **≥ 1/100, <1/10**	**Not known[a]** **(cannot be estimated from the available data)**
Blood and lymphatic system			Transient thrombocytopenia, transient lymphadenopathy
Immune system disorder			Allergic reactions, in rare cases leading to shock, angioedema
Nervous system disorders	Drowsiness/ fussiness		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	Sweating		Generalised skin reactions including pruritus, urticaria or non-specific rash
Metabolism and nutrition disorders	Appetite loss		
Gastrointestinal disorders	Diarrhoea/vomiting		
Psychiatric disorders	Irritability		
Musculoskeletal and connective tissue disorders	-	-	-
General disorders and administration site conditions	Fever Local reactions: pain, redness	Local reactions: swelling, induration, ecchymosis	

[a] Because these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to drug exposure

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. Healthcare professionals are asked to report any suspected adverse reactions https://pophealth.my.site.com/carmreportnz/s/.

4.9 Overdose

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

For further advice on management of overdose please contact the National Poisons Information Centre (0800 POISON or 0800 764 766).

5. Pharmacological Properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Influenza vaccine, ATC Code: J07BB02.

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, randomised, observer-blind, non-influenza vaccine comparator-controlled, multicentre, multi-country (Europe and Asia) in subjects aged 6 months 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 season 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 strains 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 ((%% CI: 0.45 to 0.81).

Table: Absolute vaccine efficacy of Influvac Tetra in the prevention of symptomatic influenza infection due to any seasonal influenza strains 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 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 was consistent across age groups and 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). A 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. In study INFQ3003, the HI titers after vaccination were consistently higher in the Influvac Tetra group compared with the non-influenza vaccine group.

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: 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: 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: 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 NH 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 NH 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 SH 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

Non-clinical data revealed no special hazard for humans based on conventional studies of repeat dose and local toxicity, reproductive and developmental toxicity and safety pharmacology studies.

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
- 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 nanograms ovalbumin
- 0.01 mg formaldehyde
- 0.02 mg cetrimonium bromide
- 1 mg sodium citrate
- 0.2 mg sucrose
- 1 nanograms 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.

6.3 Shelf life

1 year from the date of manufacture.

6.4 Special precautions for storage

Keep out of the sight and reach of children.

Store between 2 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

0.5 mL suspension for injection in pre-filled syringe with or without 16 mm or 25 mm needle (glass, type I), in packs of 1 or 10.

Not all presentations and pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Influvac Tetra should be allowed to reach room temperature and shaken well before use.

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

7. Medicines Schedule

Prescription Medicine

8. Sponsor Details

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AUCKLAND
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9. Date of First Approval

19 October 2017

10. Date of Revision of the Text

12 November 2024

Summary table of changes

Section	Summary of new information
4.3	Updated to include exception for hypersensitivity to egg proteins.
4.4	Added information on vaccination in individuals with egg allergy.
6.1	Added trace amounts of chicken proteins.