NEW ZEALAND DATA SHEET

For Season 2026

1 PRODUCT NAME

Flucelvax® (Influenza virus haemagglutinin)
Trivalent influenza vaccine (surface antigen, inactivated, prepared in cell cultures), suspension for injection 45 micrograms per 0.5 mL containing Influenza virus haemagglutinin as active ingredient.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

This is a purified, inactivated, subunit influenza vaccine. Each 0.5 mL dose contains influenza virus surface antigens (haemagglutinin and neuraminidase)*, for the 2026 influenza season representative of the following types:

A/Missouri/11/2025 (H1N1)pdm09-like virus (A /Tasmania/318/2025 CVR-351)	15 micrograms HA**
A/Sydney/1359/2024 (H3N2)-like virus (A/Singapore/GP20238/2024)	15 micrograms HA**
B/Austria/1359417/2021-like virus (B/Singapore/WUH4618/2021)	15 micrograms HA**

per 0.5 mL dose

* propagated in Madin Darby Canine Kidney (MDCK) cells
** haemagglutinin

Flucelvax® is prepared in MDCK cells, adapted to grow freely in suspension in culture medium. The virus is inactivated with ß-propiolactone, disrupted by the detergent cetyltrimethylammonium bromide and purified through several process steps. Therefore Flucelvax® may contain traces of propiolactone, cetyltrimethylammonium bromide, and polysorbate 80 (refer to Section **4.3 Contraindications**). Eggs are not used in the manufacturing process, therefore, Flucelvax® does not contain egg proteins. For the full list of excipients, see Section **6.1 List of excipients**.

The vaccine complies with the World Health Organization (WHO) recommendation and Australian Influenza Vaccine Committee (AIVC) and the New Zealand Ministry of Health for the 2026 Southern Hemisphere Influenza season. The strains chosen for vaccine manufacture are endorsed by the AIVC as being antigenically equivalent to the reference virus.

3 PHARMACEUTICAL FORM

Flucelvax® is a clear to slightly opalescent suspension for injection.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the prevention of influenza caused by Influenza Virus, Types A and B contained in the vaccine. The vaccine is indicated for use in adults and children 6 months of age and older.

For full details regarding recommendations for influenza vaccination, please refer to the relevant national immunisation guidelines.

4.2 Dose and method of administration

Dose

Age Group	Dose	Schedule
Paediatrics		
6 months to < 9 years	One or two[a] 0.5 mL doses	If 2 doses, administer at least 4 weeks apart
9 to < 18 years	One 0.5 mL dose	Not applicable
Adults		
≥ 18 years	One 0.5 mL dose	Not applicable

[a] Children less than 9 years of age who have not been previously vaccinated against influenza, should receive a second dose.

Method of administration

Flucelvax® should be administered by intramuscular injection only. **The vaccine must not be injected intravascularly, subcutaneously or intradermally.**

The preferred site for intramuscular injection is the deltoid muscle of the upper arm. Younger children with insufficient deltoid mass should be vaccinated in the anterolateral aspect of the thigh.

Flucelvax® must not be mixed with other vaccines in the same syringe.

Shake before use. After shaking, the vaccine should appear as a clear to slightly opalescent suspension.

Visually inspect the contents of each pre-filled syringe for particulate matter and/or variation in appearance prior to administration. If either condition is observed, do not administer the vaccine.

Flucelvax® does not contain preservatives or antibiotics. Each pre-filled syringe is for use in one patient on one occasion only. Discard any residue.

4.3 Contraindications

The vaccine is contraindicated in individuals with known severe allergic reactions (e.g. anaphylaxis) to:

- any component of the vaccine (refer to Section **2. QUALITATIVE AND QUANTITATIVE COMPOSITION &** Section **6.1 List of excipients**) or
- a previous dose of any influenza vaccine.

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 febrile illness until the fever is resolved.

In immunocompromised patients the antibody response may be lower.

A protective immune response may not be elicited in all vaccine recipients.

If Guillain-Barré syndrome has occurred within 6 weeks of previous influenza vaccination, the decision to give Flucelvax® vaccine should be based on careful consideration of the potential benefits and risks.

The syringe and all associated syringe components for Flucelvax® pre-filled syringe needle-free do not contain natural rubber latex.

Flucelvax® pre-filled syringe with attached needle cannot be considered to be latex-free as the sheath covering the needle may contain natural rubber latex, refer to statement on carton. See Section **6.5 Nature and contents of container** for further information.

Data for Flucelvax® Quad are relevant to Flucelvax® because both vaccines are manufactured using the same process and have overlapping compositions.

Use in the elderly

Of the total number of subjects who received one dose of Flucelvax® Quad in clinical studies and were included in the safety population (2493), 26.47% (660) were 65 years of age and older and 7.7% (194) were 75 years of age or older.

Antibody responses to Flucelvax® Quad were lower in the geriatric (adults 65 years and older) population than in younger subjects.

Paediatric use

Flucelvax® is not indicated in children less than 6 months of age.

Effects on laboratory tests

No data available.

4.5 Interactions with other medicines and other forms of interactions

Based on clinical experience Flucelvax® can be given at the same time as other vaccines. If Flucelvax® is to be given at the same time as another injectable vaccine(s), the vaccine(s) should always be administered to separate limbs. It should be noted that adverse reactions may be intensified.

4.6 Fertility, pregnancy and lactation

Data for Flucelvax® Quad are relevant to Flucelvax® because both vaccines are manufactured using the same process and have overlapping compositions.

Effects on fertility

A reproductive and developmental toxicity study in which female rabbits were administered 45 mcg HA/dose, 3 times prior to mating and twice during gestation, showed no adverse effects on the mating performance or female fertility. Male fertility has not been assessed in animals.

Use in pregnancy – Pregnancy Category A

The safety of Flucelvax® in pregnancy has not been assessed in randomised clinical trials. A prospective Pregnancy Exposure Registry was conducted in the United States (US) and data were collected from 665 women vaccinated with Flucelvax® Quad during 3 Northern Hemisphere influenza seasons (2017-18 to 2019-20), of whom 28% were exposed during their first trimester. Based on pregnancy outcomes and predefined infant safety outcomes, there was no evidence of adverse foetal, newborn or pregnancy outcomes attributable to the vaccine during any stage of pregnancy.

Reproductive and developmental toxicity data do not predict an increased risk of developmental abnormalities. In a reproductive and developmental toxicity study the effect of cell culture-derived antigens on embryo-foetal development was evaluated in pregnant rabbits. Anti-influenza antibodies were detected in treated rabbits and their offspring. No adverse effects on pregnancy or embryo-foetal development were observed.

Influenza vaccination is recommended for pregnant women during any stage of pregnancy. This recommendation is based on the known adverse consequences of influenza infection during pregnancy and the large body of data showing that large numbers of women have been vaccinated during pregnancy with inactivated influenza vaccines with no increased risk of adverse foetal or maternal outcomes attributable to the vaccine. Flucelvax® vaccine should be given to a pregnant woman following an assessment of the risks and benefits.

Use in lactation

Flucelvax® has not been evaluated in nursing mothers. No data are available on the use of Flucelvax® during lactation.

4.7 Effects on ability to drive and use machines

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 Undesirable effects

Clinical trials

Because clinical trials are conducted under very specific conditions, the adverse event rates observed in the clinical trials may not reflect the rates observed in the clinical studies of another vaccine and may not reflect the rates of events observed in clinical practice.

Data for Flucelvax® Quad are relevant to Flucelvax® because both vaccines are manufactured using the same process and have overlapping compositions.

Adults 18 years of age and older

The safety of Flucelvax® Quad in adults 18 years and older was evaluated in a randomised, double-blind, controlled study conducted in the US (NCT01992094, see http://clinicaltrials.gov) (Study V130_01). The safety population included a total of 2680 adults 18 years of age and older; 1340 adults 18 to < 65 years of age and 1340 adults 65 years of age and older. In this study, subjects received Flucelvax® Quad or one of the two formulations of comparator trivalent influenza vaccine (Flucelvax® Quad N=1334, TIV1c [B-Victoria] N=677 or TIV2c [B-Yamagata] N=669).

In this study, solicited local injection site and systemic adverse events were collected from subjects who completed a symptom diary card for 7 days following vaccination. Unsolicited adverse events were collected for 21 days after vaccination. Serious adverse events (SAEs) were collected throughout the study duration (until 6 months after vaccination). All adverse events are presented regardless of any treatment causality assigned by study investigators.

Solicited adverse events in the safety population of adults 18 to < 65 years of age and 65 years of age and older are shown in **Table 1**.

Table 1: Incidence of Solicited Adverse Events[1] in the Adult and Elderly Safety Population[2] Reported Within 7 Days of Vaccination (Study V130_01)

	Percentages of Subjects with Any (Severe) Solicited Events[3]					
	18 to < 65 years of age			≥ 65 years of age		
	Flucelvax® Quad N=663	Trivalent Influenza Vaccine		Flucelvax® Quad N=656	Trivalent Influenza Vaccine	
		TIV1c[4] N=330	TIV2c[4] N=327		TIV1c[4] N=340	TIV2c[4] N=336
Local Adverse Events						
Injection site pain	45 (< 1)	37 (< 1)	41 (0)	22 (0)	19 (0)	19 (0)
Injection site erythema	13 (0)	13 (0)	10 (0)	12 (0)	11 (0)	10 (0)
Injection site induration	12 (0)	10 (< 1)	10 (0)	9 (0)	7 (0)	8 (0)
Injection site ecchymosis	4 (0)	3 (< 1)	5 (0)	5 (0)	4 (0)	5 (0)
Systemic Adverse Events						
Headache	19 (< 1)	19 (< 1)	19 (< 1)	9 (< 1)	9 (< 1)	8 (< 1)
Fatigue	18 (< 1)	22 (< 1)	16 (2)	9 (< 1)	11 (< 1)	9 (< 1)
Myalgia	15 (< 1)	15 (< 1)	15 (1)	8 (< 1)	9 (< 1)	8 (< 1)
Nausea	10 (< 1)	7 (< 1)	9 (1)	4 (< 1)	4 (0)	4 (< 1)
Arthralgia	8 (< 1)	8 (0)	10 (< 1)	6 (< 1)	5 (< 1)	7 (< 1)
Loss of appetite	8 (< 1)	9 (< 1)	8 (< 1)	4 (< 1)	5 (0)	4 (< 1)
Diarrhoea	7 (< 1)	8 (0)	8 (< 1)	4 (< 1)	5 (< 1)	5 (< 1)
Chills	6 (< 1)	6 (< 1)	6 (0)	4 (< 1)	4 (< 1)	5 (< 1)
Vomiting	3 (0)	2 (< 1)	< 1(0)	< 1 (< 1)	< 1 (0)	< 1(0)
Fever: ≥38.0 °C (≥40.0°C)	< 1 (0)	< 1 (0)	< 1 (0)	< 1 (0)	< 1 (0)	< 1 (0)

[1] All solicited local and systemic adverse events reported within 7 days of vaccination are included.
[2] Safety population: all subjects in the exposed population who provided post-vaccination safety data.
[3] Percentage of severe adverse events are presented in parenthesis.
[4] TIV1c contained B-Victoria strain and TIV2c contained B-Yamagata strain.

Definition of severe events: Erythema, Induration and Ecchymosis: Severe= > 100 mm; Pain and systemic adverse events: Severe = unable to perform daily activity.

The most commonly reported unsolicited adverse events (reported by ≥ 3% of subjects administered Flucelvax® Quad) in adults 18 to < 65 years, were upper respiratory tract infection (3.5%; TIV1c 2.7%; TIV2c 4.6%) and nasopharyngitis (3.0%; TIV1c 2.4%; TIV2c 2.7%). In adults ≥ 65 years, the most commonly reported unsolicited adverse events (reported by ≥ 3% of subjects administered Flucelvax® Quad) were nasopharyngitis (4.4%; TIV1c 4.1%; TIV2c 3.3%)) and upper respiratory tract infection (3.3%; TIV1c 3.5%; TIV2c 3.3%).

There were no serious adverse events assessed as being related to study vaccines.

Children and Adolescents 6 months to less than 18 years of age

Flucelvax® is indicated for use in adults and children 6 months of age and older (See Section **4.1 Therapeutic indications**).

The safety of Flucelvax® Quad in children 6 months to less than 18 years of age has been evaluated in studies V130_03, V130_12 and V130_10.

Study V130_03 was a randomised, double-blind, controlled study in children 4 to less than 18 years conducted in the US (NCT01992107, see http://clinicaltrials.gov). The safety population included a total of 2332 children 4 to less than 18 years of age; 1161 children 4 to less than 9 years of age and 1171 children 9 to less than 18 years of age. In this study, subjects received Flucelvax® Quad or one of the two formulations of comparator trivalent influenza vaccine (Flucelvax® Quad N=1159, TIV1c [B-Victoria] N=593 or TIV2c [B-Yamagata] N=580).

Study V130_12 was a multinational, randomised, observer-blind study in children 2 to less than 18 years of age (NCT03165617, see http://clinicaltrials.gov). The safety population included a total of 4509 children 2 to less than 18 years of age who received Flucelvax® Quad (N=2255) or a non-influenza comparator vaccine (N=2254).

In these studies, children 9 to less than 18 years of age received a single dose of Flucelvax® Quad or comparator vaccine. Children less than 9 years of age received one or two doses (separated by 4 weeks) of Flucelvax® Quad or comparator vaccine depending on the subject's prior influenza vaccination history. In study V130_12, children in the 2-dose comparator group received a non-influenza comparator vaccine as the first dose and saline placebo as the second dose.

Study V130_10 was a randomised, observer-blind, multicentre safety and immunogenicity study in children 6 months to less than 4 years of age conducted in the US (NCT04074928, see http://clinicaltrials.gov). The safety population included a total of 2402 children 6 months to less than 4 years of age who received Flucelvax® Quad (N=1597) or a quadrivalent influenza comparator (N=805). Study subjects received one or two doses (separated by 4 weeks) of Flucelvax® Quad or the comparator vaccine depending on the subject's prior influenza vaccination history.

In the paediatric studies, solicited local injection site and systemic adverse events were collected from subjects who completed a symptom diary card for 7 days following vaccination. Unsolicited adverse events were collected for 28 days after each vaccination for Study V130_10 and 21 days after each vaccination for studies V130_03 and V130_12. Serious adverse events (SAEs) were collected throughout the study duration (until 6 months after last

vaccination or end of the influenza season, whichever was longer). All adverse events are presented regardless of any treatment causality assigned by study investigators.

Solicited adverse events in the safety population of children 4 years to less than 18 years of age in study V130_03 are shown in **Table 2** (4 to less than 6 years of age) and **Table 3** (6 to less than 18 years), children 2 to less than 18 years of age in study V130_12 are shown in **Table 4** and for children 6 months to less than 4 years of age in Study V130_10 are shown in **Table 5**.

Table 2: Incidence of Solicited Adverse Events[1] in the Safety Population[2] (Children 4 to less than 6 years of age) Reported After Any Dose Within 7 Days of Vaccination (Study V130_03)

	Children 4 to < 6 years		
	Percentages of Subjects with Any (Severe) Solicited Events[3]		
	Flucelvax® Quad N=182	Trivalent Influenza Vaccine	
		TIV1c[4] N=91	TIV2c[4] N=94
Local Adverse Events			
Injection site tenderness	54 (2)	51 (1)	48 (2)
Injection site erythema	23 (2)	24 (1)	20 (0)
Injection site induration	15 (1)	22 (2)	14 (0)
Injection site ecchymosis	11 (1)	12 (0)	9 (0)
Systemic Adverse Events			
Sleepiness	21 (1)	13 (3)	14 (1)
Irritability	19 (2)	14 (2)	15 (1)
Change in eating habits	14 (1)	8 (4)	7 (0)
Chills	7 (1)	3 (0)	2 (0)
Vomiting	5 (0)	2 (0)	2 (0)
Diarrhoea	5 (0)	3 (0)	4 (0)
Fever: ≥ 38.0°C (≥ 40.0°C)	5 (0)	5 (0)	3 (0)

[1] All solicited local and systemic adverse events reported within 7 days of vaccination are included

[2] Safety population: all subjects in the exposed population who provided post-vaccination safety data

[3] Percentage of subjects with severe adverse reactions are presented in parenthesis.

[4] TIV1c contained B-Victoria strain and TIV2c contained B-Yamagata strain.

Definition of severe events: Erythema, Induration and Ecchymosis: Severe = >50 mm; Pain and systemic adverse events: Severe = unable to perform daily activity.

Table 3: Incidence of Solicited Adverse Events[1] in the Safety Population[2] (Children 6 to less than 18 years of age) Reported After Any Dose Within 7 Days of Vaccination (Study V130_03)

	Percentage of Subjects with Any (Severe) Solicited Events					
	Children 6 to ≤ 9 years			Children 9 to < 18 years[3]		
	Flucelvax® Quad N=373-374[6]	Trivalent Influenza Vaccine		Flucelvax® Quad N=579	Trivalent Influenza Vaccine	
		TIV1c[4] N=185	TIV2c[4] N=187		TIV1c[4] N=294	TIV2c[4] N=281-282[5]
Local Adverse Events						
Injection site pain	61 (1)	69 (1)	68 (3)	58 (1)	51 (< 1)	50 (0)
Injection site erythema	25 (< 1)	26 (1)	25 (0)	19 (< 1)	17(0)	15 (< 1)
Injection site induration	19 (0)	22 (1)	16 (0)	15 (0)	15 (0)	13 (< 1)
Injection site ecchymosis	11 (0)	11 (0)	11 (0)	4 (0)	5 (0)	5 (0)
Systemic Adverse Events						
Headache	16 (1)	16 (0)	14 (1)	22 (1)	23 (2)	18 (1)
Fatigue	16 (2)	18 (1)	19 (0)	18 (< 1)	16 (1)	16 (< 1)
Myalgia	15 (1)	18 (1)	13 (0)	16 (< 1)	17 (< 1)	15 (< 1)
Loss of appetite	10 (< 1)	9 (0)	10 (1)	9 (0)	9 (< 1)	9 (0)
Nausea	9 (1)	7 (0)	7 (1)	9 (< 1)	8 (1)	7 (1)
Fever: ≥ 38.0°C (≥ 40.0°C)	6 (0)	4 (0)	3 (0)	1 (< 1)	3 (0)	1 (0)
Arthralgia	5 (0)	7 (1)	5 (0)	6 (0)	6 (0)	8 (< 1)
Vomiting	5 (1)	4 (0)	4 (0)	2 (0)	1 (0)	2 (0)
Diarrhoea	4 (< 1)	8 (1)	5 (0)	4 (0)	4 (0)	3 (< 1)
Chills	4 (1)	5 (1)	4 (0)	7 (0)	6 (1)	4 (1)

[1] All solicited local and systemic adverse events reported within 7 days of vaccination are included.

[2] Safety population: all subjects in the exposed population who provided post-vaccination safety data.

[3] Percentage of severe adverse events are presented in parenthesis.

[4] TIV1c contained B-Victoria strain and TIV2c contained B-Yamagata strain

[5] 281 subjects provided data for Injection site ecchymosis.

[6] 373 subjects provided data for Injection site pain.

Definition of severe events: Erythema, Induration and Ecchymosis: Severe= > 100 mm; Pain and systemic adverse events: Severe = unable to perform daily activity.

The incidence of local and systemic solicited adverse events in children 2 to less than 18 years of age who received Flucelvax® Quad or the non-influenza comparator vaccine in Study V130_12 are presented in **Table 4**.

Table 4: Incidence of Solicited Adverse Events[1] in the Safety Population[2] (Children 2 to less than 18 years of age) Reported After Any Dose Within 7 Days of Vaccination (Study V130_12)

	Percentages of Subjects with Any (Severe) Solicited Events[3]					
	Children 2 to < 6 years		Children 6 to < 9 years		Children 9 to < 18 years	
	FLUCELVAX® QUAD N=580	Comparator[4] N=565	FLUCELVAX® QUAD N=564	Comparator[4] N=578	FLUCELVAX® QUAD N=1111	Comparator[4] N=1111
Local Adverse Events						
Injection site pain/Tenderness	28.7 (1.0)	25.4 (1.4)	27.9 (1.2)	20.3 (1.6)	21.7 (0.5)	18.3 (1.0)
Injection site erythema	20.2 (0.3)	24.5 (1.8)	22.4 (0.4)	22.8 (0.3)	17.2 (0)	18.7 (0.5)
Injection site induration	13.5 (0.2)	13.9 (0.7)	16.3 (0.2)	16.5 (0.2)	10.5 (0.1)	11 (0.2)
Injection site ecchymosis	9.2 (0)	6.9 (0)	10.9 (0)	8.0 (0.2)	5.0 (0)	5.2 (0)
Systemic Adverse Events						
Sleepiness	14.9 (0.9)	17.6 (1.8)	-	-	-	-
Irritability	13.8 (0.2)	10.8 (0.5)	-	-	-	-
Fatigue	-	-	13.8 (0.9)	12.7 (0.7)	17 (1.1)	18.2 (1.2)
Headache	-	-	13.8 (0.4)	11.8 (0.5)	18.1 (1.4)	17.4 (0.6)
Loss of appetite	-	-	10.6 (0.5)	8.0 (0.5)	8.5 (0.5)	7.5 (0.5)
Change of eating habits	9.9 (1.0)	10.1 (0.7)	-	-	-	-
Fever: ≥ 38.0°C (≥ 40.0°C)	8.8 (0.5)	7.7 (0.4)	6.4 (0.5)	4.5 (0)	2.8 (0.1)	3.0 (0.3)
Diarrhoea	8.3 (0.5)	8.5 (0.9)	4.6 (0.4)	5.2 (0.3)	7.4 (0.5)	8.1 (0.3)
Arthralgia	-	-	5.2 (0.4)	6.2 (0.3)	7.1 (0.4)	8.4 (0.5)
Nausea	-	-	5.2 (0)	4.5 (0.7)	6.0 (0.2)	6.1 (0.6)
Vomiting	4.8 (0.5)	4.1 (0.7)	5.0 (0.7)	4.2 (0.5)	3.0 (0.3)	3.0 (0.4)
Chills/Shivering	4.7 (0.7)	3.9 (0.4)	6.1 (0.5)	3.8 (0.3)	7.6 (0.4)	7.6 (0.3)
Myalgia	-	-	2.9 (0.2)	4.0 (0.3)	6.1 (0.5)	5.5 (0.5)

[1] All solicited local and systemic adverse events reported from 6 hours post-vaccination to 7 days after vaccination are included.

[2] Solicited Safety Population: subjects who were vaccinated and provided any solicited local or systemic adverse event safety data, from 6 hours through 7 days after vaccination

[3] Percentage of subjects with severe adverse events are presented in parenthesis

[4] Meningococcal (Group ACWY) Conjugate Vaccine

Definitions of severe adverse events (subjects 2 to < 6 years of age): Erythema, Induration and Ecchymosis: > 50 mm; Tenderness and Shivering: prevents daily activity; Change of eating habits: Missed more than 2 feeds/meals; Sleepiness: Sleeps most of the time and is hard to arouse him/her; Vomiting: 6 or more times in 24 hours or requires intravenous hydration; Diarrhoea: 6 or more loose stools in 24 hours or requires intravenous hydration; Irritability: unable to console.

Definitions of severe adverse events (subjects 6 to < 18 years of age): Erythema, Induration and Ecchymosis: > 100 mm; Loss of appetite: Not eating at all; Vomiting: 6 or more times in 24 hours or requires intravenous hydration; Diarrhoea: 6 or more loose stools in 24 hours or requires intravenous hydration; Pain, Nausea, Fatigue, Myalgia, Arthralgia, Headache and Chills: prevents daily activity.

"-" denotes adverse events was not solicited in this age group.

The incidence of local and systemic solicited adverse events in children 6 months to less than 4 years of age who received Flucelvax® Quad or influenza comparator vaccine in Study V130_10 are presented in **Table 5**.

Table 5: Incidence of Solicited Adverse Events[1] in the Safety Population[2] (Children 6 months to less than 4 years of age) Reported After Any Dose Within 7 Days of Vaccination (Study V130_10)

	Percentages of Subjects with Any (Severe) Solicited Reactions[3]			
	Children 6 to <24 months		Children 24 to <48 months	
	Flucelvax® Quad N=581	Comparator QIV N=292	Flucelvax® Quad N=983	Comparator QIV N=492
Local Adverse Events				
Injection site tenderness	25.5 (2.1)	23.3 (1.4)	29.3 (2.2)	33.9 (1.4)
Injection site erythema	25.3 (0)	18.2 (0)	26.0 (0.7)	28.5 (0)
Injection site induration	16.5 (0.5)	12.0 (0)	17.7 (0.3)	18.3 (0)
Injection site ecchymosis	11.2 (0.2)	7.5 (0)	10.5 (0.1)	12.8 (0)
Systemic Adverse Events				
Irritability	35.1 (5.2)	35.6 (2.1)	23.6 (1.8)	26.0 (3.0)
Sleepiness	35.5 (2.4)	30.5 (1.7)	21.8 (1.9)	22.6 (1.2)
Diarrhoea	23.2 (2.4)	20.2 (0.7)	14.8 (1.1)	14.0 (1.2)
Change of eating habits	21.0 (1.7)	21.9 (2.4)	15.3 (1.4)	15.0 (1.2)
Fever: ≥38.0 °C (≥40.0 °C)	9.3 (0.7)	10.3 (0)	5.4 (0.6)	4.9 (0.2)
Vomiting	10.5 (0.7)	6.8 (0.7)	4.6 (0.5)	5.9 (0.4)
Shivering	3.1 (0.2)	3.1 (0)	3.3 (0.2)	3.7 (0)

[1]All solicited local and systemic adverse events reported from Day 1 through Day 7 after vaccination are included

[2] Safety population: all subjects in the exposed population who provided post-vaccination safety data.

[3] Percentage of subjects with severe adverse events are presented in parenthesis.

Definition of severe local events: For induration, ecchymosis, and erythema, severe was defined as >50 mm. For tenderness severe was defined as “Cried when limb was moved/spontaneously painful” in subjects <24 months of age at time of first dose of vaccine and "Prevents daily activity" in subjects 24 months of age and older at time of first dose of vaccine.

Definition of severe systemic events: Severe change of eating habits was defined as “missed more than 2 feeds/meals”; severe sleepiness was defined as “sleeps most of the time and it is hard to arouse him/her”; severe vomiting or throwing up was defined as “6 or more times in 24 hours or requires intravenous hydration”; severe loose stools or diarrhoea was defined as “6 or more loose stools in 24 hours or requires intravenous hydration”; severe irritability was defined as “unable to console”; severe shivering was defined as “prevents daily activity”.

In study V130_03, the most commonly reported unsolicited adverse event (reported by ≥ 3% of subjects administered Flucelvax® Quad) in children 4 to less than 18 years of age (regardless of treatment causality), was cough (3.0%), with a similar frequency reported for the trivalent influenza vaccine comparators (TIV1c 4.0%; TIV2c 3.0%).

In study V130_12, the most commonly reported unsolicited adverse events (reported by ≥ 3% of subjects administered Flucelvax® Quad) in children 2 to less than 18 years of age (regardless of causality), and with a similar frequency to the non-influenza comparator vaccine were influenza-like illness (9.4%; Comparator 8.9%), upper respiratory tract infection (4.5%; Comparator 4.1%), cough (3.4%; Comparator 3.2%) and rhinitis (3.4%; Comparator 3.8%).

In study V130_10, the most commonly reported unsolicited adverse events (reported by ≥ 3% of subjects administered Flucelvax® Quad) in children 6 months to less than 4 years of age (regardless of causality), were upper respiratory tract infection (3.7%; Comparator 5.5%) and pyrexia (2.9%; Comparator 3.1%).

In children who received two doses, the rates of solicited local and systemic adverse events was generally similar or lower after the second dose compared to the first dose.

In children 6 months to less than 18 years of age, there were no serious adverse events assessed as being related to study vaccines in either Study V130_03, Study V130_12 or Study V130_10.

Post-marketing adverse reactions

The following events have been identified during post-approval use of Flucelvax® Quad and Flucelvax®:

General disorders and administration site conditions

Extensive swelling of injected limb.

Immune system disorders

Allergic or immediate hypersensitivity reactions, including anaphylactic shock.

Nervous system disorders

Paraesthesia, syncope, presyncope, Guillain-Barré syndrome, febrile convulsions.

Skin and subcutaneous tissue disorders

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

Reporting suspected adverse effects

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

There is no experience of overdose with Flucelvax®.

For risk assessment and advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Influenza Vaccines
ATC Code: J07BB02

5.1 Pharmacodynamic properties

Mechanism of action

Influenza illness and its complications follow infection with influenza viruses. Global surveillance and analysis of influenza virus isolates permits identification of yearly antigenic variants. Specific levels of haemagglutination inhibition (HI) antibody titres post-vaccination with inactivated influenza vaccine have not been correlated with protection from influenza virus. In some human studies, antibody titres of 1:40 or greater have been associated with protection from influenza illness in up to 50% of subjects. Antibody against one influenza virus type or subtype confers limited or no protection against another. Furthermore, antibody to one antigenic variant of influenza virus might not protect against a new antigenic variant of the same type or subtype.

Annual revaccination with current influenza vaccines is recommended because immunity declines during the year after vaccination and circulating strains of influenza virus may change from year to year.

Clinical trials

Data for Flucelvax® Quad are relevant to Flucelvax® because both vaccines are manufactured using the same process and have overlapping compositions.

Efficacy against Culture-Confirmed Influenza

Study V58P13

A multinational (US, Finland and Poland), randomised, observer-blinded, placebo-controlled trial was performed to assess clinical efficacy and safety of Flucelvax® during the 2007-2008 influenza season in adults aged 18 to 49 years (NCT00630331, see http://clinicaltrials.gov). A total of 11,404 subjects were enrolled to receive Flucelvax® (N=3828), Agrippal (N=3676) or placebo (N=3900) in a 1:1:1 ratio. Among the overall study population enrolled, the mean age was 33 years, 55% were female, 84% were Caucasian, 7% were Black, 7% were Hispanic, and 2% were of other ethnic origin.

Flucelvax® efficacy was defined as the prevention of culture-confirmed symptomatic influenza illness caused by viruses antigenically matched to those in the vaccine compared to placebo. Influenza cases were identified by active and passive surveillance of influenza-like illness (ILI). ILI was defined according to Centers for Disease Control and Prevention (CDC) case definition, i.e., a fever (oral temperature ≥ 100.0°F / 38°C) and cough or sore throat. After an

episode of ILI, nose and throat swab samples were collected for analysis. Vaccine efficacies against vaccine-matched influenza viral strains, against all influenza viral strains, and against individual influenza viral subtypes were calculated (**Table 6**).

Table 6: Efficacy of Flucelvax® against culture confirmed influenza by influenza viral subtype (Study V58P13)

		Flucelvax® (N=3776)		Placebo (N=3843)		Vaccine Efficacy*	
		Attack Rate (%)	Number of Subjects with Influenza	Attack Rate (%)	Number of Subjects with Influenza	%	Lower Limit of One- Sided 97.5% CI
Antigenically Matched Strains							
Overall		**0.19**	**7**	**1.14**	**44**	**83.8**	**61.0**
Individual strains	**A/H3N2****	0.05	2	0	0	--	--
	A/H1N1	0.13	5	1.12	43	88.2	67.4
	B**	0	0	0.03	1	--	--
All Culture-Confirmed Influenza							
Overall		**1.11**	**42**	**3.64**	**140**	**69.5**	**55.0**
Individual strains	**A/H3N2**	0.16	6	0.65	25	75.6	35.1
	A/H1N1	0.16	6	1.48	57	89.3	73.0
	B	0.79	30	1.59	61	49.9	18.2

* Simultaneous one-sided 97.5% confidence intervals for the vaccine efficacy of each influenza vaccine relative to placebo based on the Sidak-corrected score confidence intervals for the two relative risks.
Vaccine Efficacy = (1 - Relative Risk) x 100 %;

** There were too few cases of influenza due to vaccine-matched influenza A/H3N2 or B to adequately assess vaccine efficacy.

Immunogenicity

Adult Studies

Study V130_01

Immunogenicity of Flucelvax® Quad was evaluated in adults 18 years of age and older in a randomised, double-blind, controlled study conducted in the US (NCT01992094, see http://clinicaltrials.gov). In this study, subjects received Flucelvax® Quad or one of the two formulations of comparator trivalent influenza vaccine (Flucelvax® Quad N=1334, TIV1c [B-Victoria] N=677 or TIV2c [B-Yamagata] N=669). In the per protocol set, the mean age of subjects who received Flucelvax® Quad was 57.5 years; 55.1% of subjects were female and

76.1% of subjects were Caucasian, 13% were Black and 9% were Hispanic. The immune response to each of the vaccine antigens was assessed, 21 days after vaccination.

The immune response of Flucelvax® Quad was non-inferior to TIVc for all 4 influenza strains (geometric mean titre (GMT) and differences in vaccine group seroconversion rates).

Non-inferiority criteria were also met for all 4 influenza strains in age subgroup analyses for subjects 18 to less than 65 years of age and 65 years of age and above.

The non-inferiority data observed are summarised in **Table 7**.

Table 7: Non-inferiority of Flucelvax® Quad relative to TIVc in adults 18 years of age and above – Per protocol analysis set (Study V130_01)

		Flucelvax® Quad N = 1250	TIV1c/TIV2c[a] N = 635/N =639	Vaccine group Ratio (95% CI)	Vaccine Group Difference (95% CI)
A/H1N1	GMT at Day 1 (95% CI)	60.7 (56.0-65.9)	59.6 (53.0-67.0)	-	-
	GMT at Day 22 (95% CI)	302.8 (281.8-325.5)	298.9 (270.3-330.5)	1.0 (0.9-**1.1**)	-
	Seroconversion Rate[b] (95% CI)	49.2% (46.4-52.0)	48.7% (44.7-52.6)	-	-0.5% (-5.3-**4.2**)
	Seroprotection Rate[c] (95% CI)	96.3% (95.1-97.3)	96.7% (95.0-97.9)	-	-
A/H3N2	GMT at Day 1 (95% CI)	122.5 (112.7-133.1)	128.1 (113.6-144.6)	-	-
	GMT at Day 22 (95% CI)	372.3 (349.2-396.9)	378.4 (345.1-414.8)	1.0 (0.9-**1.1**)	-
	Seroconversion Rate[b] (95% CI)	38.3% (35.6-41.1)	35.6% (31.9-39.5)	-	-2.7% (-7.2-**1.9**)
	Seroprotection Rate[c] (95% CI)	98.4% (97.5-99.0)	98.6% (97.3-99.3)	-	-
B1	GMT at Day 1 (95% CI)	45.3 (42.6-48.1)	43.8 (40.2-47.7)	-	-
	GMT at Day 22 (95% CI)	133.2 (125.3-141.7)	115.6 (106.4-125.6)	0.9 (0.8-**1.0**)	-
	Seroconversion Rate[b] (95% CI)	36.6% (33.9-39.3)	34.8% (31.1-38.7)	-	-1.8% (-6.2-**2.8**)
	Seroprotection Rate[c] (95% CI)	93.6% (92.1-94.9)	91.8% (89.4-93.8)	-	-
B2	GMT at Day 1 (95% CI)	59.2 (56.0-62.7)	58.0 (53.4-63.0)	-	-
	GMT at Day 22 (95% CI)	177.2 (167.6-187.5)	164.0 (151.4-177.7)	0.9 (0.9-**1.0**)	-
	Seroconversion Rate[b] (95% CI)	39.8% (37.0-42.5)	35.4% (31.7-39.2)	-	-4.4% (-8.9-**0.2**)
	Seroprotection Rate[c] (95% CI)	97.7% (96.7-98.4)	96.9% (95.2-98.1)	-	-

Abbreviations: GMT = geometric mean titre. CI = confidence interval.

[a] The comparator vaccine for non-inferiority comparisons for A/H1N1, A/H3N2 and B1 is TIV1c (containing B-Victoria), for B2 it is TIV2c (containing B-Yamagata).

[b] Seroconversion rate = percentage of subjects with either a pre-vaccination HI titre < 1:10 and postvaccination HI titre ≥ 1:40 or with a pre-vaccination HI titre ≥ 1:10 and a minimum 4-fold increase in post-vaccination HI antibody titre

[c] Seroprotection rate = percentage of subjects with HI titre ≥1:40. Seroprotection was not used for non-inferiority evaluation.

Bold = Non-inferiority criterion met

Paediatric Studies

Study V130_03

Immunogenicity of Flucelvax® Quad was evaluated in children 4 to less than 18 years of age in a randomised, double-blind, controlled study conducted in the US (NCT01992107, see http://clinicaltrials.gov). In this study, subjects received Flucelvax® Quad or one of the two formulations of comparator trivalent influenza vaccine (Flucelvax® Quad N=1159, TIV1c [B-Victoria] N=593 or TIV2c [B-Yamagata] N=580). In the per protocol set, the mean age of subjects who received Flucelvax® Quad was 9.8 years; 47% of subjects were female and 54% of subjects were Caucasian, 22% were Black and 19% were Hispanic. The immune response to each of the vaccine antigens was assessed, 21 days after vaccination.

The immune response of Flucelvax® Quad was non-inferior to TIVc for all 4 influenza strains (GMT and differences in vaccine group seroconversion rates).

The non-inferiority data observed are summarised in **Table 8** in children and adolescents aged 4 to less than 18 years.

Table 8: Non-inferiority[a] of Flucelvax® Quad relative to TIVc in children and adolescents 4 to less than 18 years of age) – Per-protocol analysis Set (Study V130_03)

		Flucelvax® Quad	TIV1c/TIV2c[b]	Vaccine Group Ratio (95% CI)	Vaccine Group Difference (95% CI)
A/H1N1		N = 1014	N = 510		
	GMT at Day 1 (95% CI)	96 (86-107)	100 (86-116)	-	-
	GMT at Day 22 or 50 (95% CI)	1090 (1027-1157)	1125 (1034-1224)	1.03 (0.93-**1.14**)	-
	Seroconversion Rate[c] (95% CI)	72% (69-75)	75% (70-78)	-	2% (-2.5- **6.9**)
	Seroprotection Rate[d] (95% CI)	99% (98%-100%)	100% (99%-100%)	-	-
A/H3N2		N = 1013	N = 510		
	GMT at Day 1 (95% CI)	206 (188-225)	196 (172-222)	-	-
	GMT at Day 22 or 50 (95% CI)	738 (703-774)	776 (725-831)	1.05 (0.97-**1.14**)	-
	Seroconversion Rate[c] (95% CI)	47% (44-50)	51% (46-55)	-	4% (-1.4- **9.2**)
	Seroprotection Rate[d] (95% CI)	100% (99%-100%)	100% (99%-100%)		
B1		N = 1013	N = 510		
	GMT at Day 1 (95% CI)	26 (24-28)	23 (21-26)	-	-
	GMT at Day 22 or 50 (95% CI)	155 (146-165)	154 (141-168)	0.99 (0.89-**1.1**)	-
	Seroconversion Rate[c] (95% CI)	66% (63-69)	66% (62-70)	-	0% (-5.5- **4.5**)
	Seroprotection Rate[d] (95% CI)	93% (91%-94%)	93% (90%-95%)	-	-
B2		N = 1009	N = 501		
	GMT at Day 1 (95% CI)	23 (21-25)	23 (21-26)	-	-
	GMT at Day 22 or 50 (95% CI)	185 (171-200)	185 (166-207)	1 (0.87-**1.14**)	-
	Seroconversion Rate[c] (95% CI)	73% (70-76)	71% (67-75)	-	-2% (-6.5- **3.2**)
	Seroprotection Rate[d] (95% CI)	92% (90%-93%)	90% (87%-93%)	-	-

Abbreviations: GMT = geometric mean titre. CI = confidence interval.

[a] Analyses are performed on data for day 22 for previously vaccinated subjects and day 50 for not previously vaccinated subjects

[b] The comparator vaccine for non-inferiority comparisons for A/H1N1, A/H3N2 and B1 is TIV1c (containing B-Victoria, for the B2 strain the comparator vaccine is TIV2c (containing B-Yamagata)

[c] Seroconversion rate = percentage of subjects with either a pre-vaccination HI titre < 1:10 and post-vaccination HI titre ≥ 1:40 or with a pre-vaccination HI titre ≥ 1:10 and a minimum 4-fold increase in post-vaccination HI antibody titre

[d] Seroprotection rate = percentage of subjects with HI titre ≥1:40. Seroprotection was not used for non-inferiority evaluation.

Bold = Non-inferiority criterion met

Study V130_10

Immunogenicity of Flucelvax® Quad was evaluated in children 6 months to less than 4 years of age in a randomised, observer-blind, multicentre study conducted in the US (NCT04074928, see http://clinicaltrials.gov). In this study, subjects received Flucelvax® Quad or a comparator quadrivalent influenza vaccine (Flucelvax® Quad N=1597, Comparator QIV N=805). In the per protocol set, the mean age of subjects was 29 months; 49% of subjects were female and 67% of subjects were Caucasian, 27% were Black and < 1% were Asian, Hawaiian or other Pacific Islander and American Indian or Alaska Native, and 26% of subjects were of Hispanic origin. The immune response to each of the vaccine antigens was assessed 28 days after last vaccination.

The immunogenicity endpoints were GMTs and percentage of subjects who achieved seroconversion, defined as a pre-vaccination HI or microneutralization (MN) titre of < 1:10 with a post-vaccination titre ≥ 1:40 or with a pre-vaccination HI or MN titre ≥ 1:10 and a minimum 4-fold increase in serum antibody titre. GMTs and seroconversion rates were measured by HI assay for A/H1N1, B/Yamagata and B/Victoria strains and by MN assay for the A/H3N2 strain.

Flucelvax® Quad was non-inferior to the comparator QIV. Noninferiority was established for all 4 influenza strains as assessed by ratios of GMTs and the differences in the percentages of subjects achieving seroconversion at 4 weeks following vaccination.

The non-inferiority data observed are summarised in **Table 9**.

Table 9: Non-inferiority[a] of Flucelvax® Quad relative to comparator QIV in children 6 months to less than 4 years of age – Per-protocol analyses set (Study V130_10)

		Flucelvax® Quad	Comparator QIV	Vaccine Group Ratio (95% CI)	Vaccine Group Difference (95% CI)
A/H1N1		N=1092	N=575		
	GMT (95% CI)	78 (71, 86)	57 (51, 65)	0.73 (0.65, **0.84**)	-
	Seroconversion Rate[b] (95% CI)	58% (55, 61)	47% (43, 51)	-	-11.5% (-16.5, **-6.4**)
A/H3N2		N=1078	N=572		
	GMT (95% CI)	23 (21, 25)	24 (22, 27)	1.04 (0.93, **1.16**)	-
	Seroconversion Rate[b] (95% CI)	28% (25, 30)	31% (27, 35)	-	3.1% (-1.4, **7.8**)
B/Yamagata		N=1092	N=575		
	GMT (95% CI)	36 (33, 39)	26 (24, 29)	0.73 (0.66, **0.81**)	-
	Seroconversion Rate[b] (95% CI)	47% (44, 50)	32% (28, 36)	-	-14.9% (-19.6, **-10.0**)
B/Victoria		N=1092	N=575		
	GMT (95% CI)	22 (21, 24)	20 (18, 22)	0.88 (0.79, **0.97**)	-
	Seroconversion Rate[b] (95% CI)	30% (28, 33)	24% (21, 28)	-	-6.0% (-10.3, **-1.4**)

Abbreviations: GMT = geometric mean titre. CI = confidence interval.

Assays: GMTs and seroconversion rates were measured by haemagglutination inhibition (HI) assay for A/H1N1, B/Yamagata and B/Victoria strains and by microneutralisation (MN) assay for the A/H3N2 strain, using cell-derived target viruses.

Bold format indicates pre-specified non-inferiority success criteria were met

Success criteria: The upper bound of the two-sided 95% confidence interval (CI) on the ratio of the GMTs (calculated as GMT comparator QIV divided by GMT Flucelvax® Quad) does not exceed 1.5. The upper bound of the two-sided 95% CI on the difference between the Seroconversion rate (calculated as Seroconversion rate comparator QIV minus Seroconversion rate Flucelvax® Quad) does not exceed 10%.

[a] Analyses are performed on data for Day 29 for previously vaccinated subjects and Day 57 for not previously vaccinated subjects

[b] Seroconversion rate = percentage of subjects with either a pre-vaccination titre < 1:10 and postvaccination titre ≥ 1:40 or with a pre-vaccination titre ≥ 1:10 and a minimum 4-fold increase in postvaccination antibody titre

Efficacy in Children (2 to less than 18 years of age)

Study V130_12

Efficacy of Flucelvax® Quad was evaluated in children 2 to less than 18 years of age in study V130_12 (NCT03165617, see http://clinicaltrials.gov). This was a multinational, randomised, non-influenza vaccine comparator-controlled efficacy study conducted in 8 countries. The study enrolled 4513 subjects who received either Flucelvax® Quad (N=2258) or a non-influenza vaccine comparator, Menveo® Meningococcal ACWY Conjugate Vaccine (N=2255). The full analysis set (FAS) for efficacy consisted of 4509 subjects.

Children 2 to less than 9 years of age received one or two doses (separated by 4 weeks) of Flucelvax® Quad or comparator vaccine depending on the subject's prior influenza vaccination history. Children 9 to less than 18 years of age received a single dose of Flucelvax® Quad or comparator vaccine. Children in the 2-dose comparator group received non-influenza comparator vaccine as the first dose and saline placebo as the second dose. Among all enrolled subjects, the mean age was 8.8 years, 49% were female, 51% were 2 to less than 9 years of age, 50% were Caucasian and 49% were Asian. There were no notable differences in the distribution of demographic and baseline characteristics between the two treatment groups.

Flucelvax® Quad efficacy was assessed by the number of confirmed influenza illness caused by any influenza Type A or B strain in the vaccine groups. Influenza cases were identified by active and passive surveillance of influenza-like illness (ILI) and confirmed by cell culture or real-time polymerase chain reaction (RT-PCR). ILI was defined as a fever (oral temperature ≥ 100.0°F / 37.8°C) along with any of the following: cough, sore throat, nasal congestion, or rhinorrhea. Overall vaccine efficacy was determined for influenza caused by any Type A or B strain (**Table 10**).

Table 10: Number of Subjects with First-Occurrence RT-PCR Confirmed or Culture Confirmed Influenza and Absolute Vaccine Efficacy (95% CI), in Subjects 2 to less than 18 Years of Age– FAS Efficacy[1] (Study V130_12)

	Number of subjects per protocol[1]	Number of cases of influenza	Attack Rate (%)	Vaccine Efficacy (VE)[2]	
				%	95% CI of VE[3]
All RT-PCR or Culture Confirmed Influenza					
Flucelvax® Quad	2257	175	7.8	54.6	45.7, 62.1
Non-Influenza Comparator[4]	2252	364	16.2	-	-
All Culture Confirmed Influenza					
Flucelvax® Quad	2257	115	5.1	60.8	51.3, 68.5
Non-Influenza Comparator[4]	2252	279	12.4	-	-
All Antigenically Matched Culture-Confirmed Influenza					
Flucelvax® Quad	2257	90	4.0	63.6	53.6, 71.5
Non-Influenza Comparator[4]	2252	236	10.5	-	-

[1] Number of subjects in the Full-Analysis Set (FAS)– Efficacy, which included all subjects randomised, received a study vaccination and provided efficacy data.

[2] Efficacy against influenza was evaluated over three influenza seasons SH 2017, NH 2017-18 and NH 2018-19

[3] Flucelvax® Quad met the pre-defined success criterion defined as the lower limit of the two-sided 95% CI of absolute vaccine efficacy greater than 20%

[4] Meningococcal (Group ACWY) Conjugate Vaccine. Children assigned to 2 doses received saline placebo as second dose

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Genotoxicity

Flucelvax® has not been evaluated for genotoxic potential.

Carcinogenicity

Flucelvax® has not been evaluated for carcinogenic potential.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Each 0.5 mL dose of Flucelvax® contains the following excipients:

Table 11: List of excipients

Sodium chloride	4 mg
Potassium chloride	0.1 mg
Magnesium chloride hexahydrate	0.05 mg
Dibasic sodium phosphate dihydrate	0.646 mg
Monobasic potassium phosphate	0.1865 mg
Water for injections	Up to 0.5 mL

Flucelvax® does not contain preservatives or antibiotics.

6.2 Incompatibilities

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 Shelf life

15 months

6.4 Special precautions for storage

Store at +2°C to +8°C. (Refrigerate. Do not freeze.) Discard if the vaccine has been frozen. Protect from light.

6.5 Nature and contents of container

Not all presentations or pack sizes may be marketed.

Pre-filled syringe – needle free

Flucelvax® (Influenza virus haemagglutinin) Suspension for Injection needle-free is a 0.5 mL suspension for injection in a needle-free pre-filled Type 1 glass syringe. The syringe and all associated syringe components do not contain natural rubber latex.

Pack sizes: 1’s, 10’s

Pre-filled syringe – attached needle

Flucelvax® (Influenza virus haemagglutinin) Suspension for Injection is a 0.5 mL suspension for injection pre-filled Type 1 glass syringe with attached needle. The sheath covering the needle may contain natural rubber latex, refer to statement on carton (See Section **4.4 Special warnings and precautions for use**.)

Pack sizes: 1's, 10's

6.6 Special precautions for disposal

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

7 MEDICINE SCHEDULE

Prescription Only Medicine

8 SPONSOR

Seqirus (NZ) Ltd
PO Box 62590
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Auckland 1546
New Zealand
Telephone: 0800 502 757

9 DATE OF FIRST APPROVAL

21 August 2025

10 DATE OF REVISION OF THE TEXT

13 February 2026

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
4.8	Include febrile convulsions in Post-marketing adverse reactions.

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