NEW ZEALAND DATA SHEET

For Season 2026

1 PRODUCT NAME

Fluad®

Inactivated trivalent influenza vaccine (surface antigen), adjuvanted, suspension for injection 45 micrograms per 0.5 mL; containing Influenza virus haemagglutinin as active ingredient.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.5 mL dose contains influenza virus surface antigens (haemagglutinin and neuraminidase) of each of three strains representative of the influenza virus types expected to circulate in the Southern Hemisphere winter according to WHO recommendations for the 2026 season:

- A/Missouri/11/2025 (H1N1)pdm09–like virus (A/Switzerland/6849/2025 IVR-278):
  15 micrograms HA*
- A/Singapore/GP20238/2024 (H3N2)–like virus (A/Singapore/GP20238/2024 IVR-277):
  15 micrograms HA*
- B/Austria/1359417/2021–like virus (B/Austria/1359417/2021 BVR-26):
  15 micrograms HA*

per 0.5 mL dose
*HA = haemagglutinin

Fluad® vaccine is prepared from virus grown in embryonated hens' eggs and inactivated with formaldehyde before purification and combination with MF59C.1, an adjuvant known to increase the immunogenicity of vaccines. MF59C.1 adjuvant is a squalene based oil-in-water emulsion. Squalene is of fish origin. It is also a normal component in the human body and is easily metabolized and excreted. For a full list of excipients, see **section 6.1 – LIST OF EXCIPIENTS**.

The type and amount of viral antigens in Fluad® conform to the requirements of the Australian Influenza Vaccine Committee and the New Zealand Ministry of Health for the 2026 Southern Hemisphere Influenza season. The strains chosen for vaccine manufacture

are endorsed by the Australian Influenza Vaccine Committee as being antigenically equivalent to the reference virus.

Fluad® is manufactured in eggs and trace amounts of kanamycin sulfate, neomycin sulfate, ovalbumin (≤ 1 micrograms/0.5 mL dose), formaldehyde (≤ 1 micrograms/0.5 mL dose), cetrimonium bromide (≤ 18 micrograms/0.5 mL dose), sucrose and hydrocortisone may be present as residues of the manufacturing process.

3 PHARMACEUTICAL FORM

Fluad® is a milky-white suspension for injection.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Active immunisation against influenza in persons 50 years 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

Fluad® is for use in adults 50 years of age and older only. See section **4.1 – THERAPEUTIC INDICATIONS**.

A single 0.5 mL dose should be administered by intramuscular injection, preferably into the deltoid muscle of the upper arm.

Gently shake before use. After shaking, the normal appearance of the vaccine is a milky-white 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.

Fluad® contains no antimicrobial preservative. Each pre-filled syringe is for use in one patient on one occasion only. Discard any residue.

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

Persons with a history of egg allergy (non-anaphylaxis) can receive a full dose of vaccine in any immunisation setting (see also section **4.4 – SPECIAL WARNINGS AND PRECAUTIONS FOR USE**).

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 **6.1 – LIST OF EXCIPIENTS**), except egg proteins (See **also** section **4.4 – SPECIAL WARNINGS AND PRECAUTIONS FOR USE**) 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 an anaphylactic event occurs following the administration of the vaccine.

Persons with a history of anaphylaxis to egg should be vaccinated only in medical facilities with staff experienced in recognising and treating anaphylaxis. For full details regarding recommendations for influenza vaccination in individuals with egg allergy, please refer to the relevant national immunisation guidelines.

Immunisation should be postponed in patients with acute febrile illness until the fever is resolved.

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

A protective 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 Fluad® should be based on careful consideration of the potential benefits and risks.

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

Fluad® pre-filled syringe with attached needle cannot be considered to be latex-free as the sheath covering the needle contains natural rubber latex, refer to statement on carton. See section **6.5 – NATURE AND CONTENTS OF CONTAINER** for further information.

Use in the elderly

Fluad® is approved for active immunisation against influenza in persons 50 years of age and older. See section **4.1 – THERAPEUTIC INDICATIONS** and also section **5 – PHARMACOLOGICAL PROPERTIES**.

Paediatric use

Paediatric data have not been evaluated.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Data from two studies on the concomitant administration of Fluad® with an approved 13-valent pneumococcal conjugate vaccine (PCV13) and an approved 23-valent pneumococcal polysaccharide vaccine (PPSV23) in an elderly population are available. These studies indicated that coadministration of Fluad® with either PCV-13 or PPSV23 did not show significant interference in antibody response. Although concomitant vaccination induced more frequent local pain, most of the local adverse reactions were mild. Systemic adverse reactions were generally mild, and no serious vaccine-related adverse events occurred.

If Fluad® needs to be used at the same time as another vaccine, immunisation should be given at separate injection sites, preferably on different limbs. It should be noted that the adverse reactions may be intensified.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available.

Use in pregnancy – Pregnancy Category B2

In a reproductive and developmental study in rabbits dosed with Fluad® twice pre-mating (21 and 7 days before mating) and during gestation (gestation day 7 and 20), there were no significant effects on the does, their fetuses or pups. The HA dose in rabbits was approximately 11-times the recommended clinical dose of a HA dose per body weight basis. Circulating anti-H1N1 antibodies were detected in the does, fetuses and pups.

There are no adequate and well-controlled studies in pregnant women. Fluad® is indicated for persons 50 years and over.

Use in lactation

No data available.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

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

4.8 UNDESIRABLE EFFECTS

The overall safety profile of Fluad® is similar to the adjuvanted quadrivalent influenza vaccine, Fluad® Quad. Data for Fluad® Quad are relevant to Fluad® because both vaccines are manufactured using the same process and have overlapping compositions.

Clinical trials

Because clinical trials are conducted under widely varying conditions, adverse event rates observed in the clinical trial(s) of a vaccine cannot be directly compared to rates in the clinical trial(s) of another vaccine and may not reflect the rates observed in practice.

Adult and Elderly Population, 50 years of age and older

Adults 50 to less than 65 years of age

The safety of Fluad® Quad in adult subjects 50 to less than 65 years of age was evaluated in clinical study V118_23. This was a randomised observer-blind, controlled, multi-centre study conducted during the 2021-2022 Northern Hemisphere influenza season. In this study, subjects received Fluad® Quad (N=1027) or a non-adjuvanted comparator quadrivalent influenza vaccine (N=1016).

Solicited local and systemic reactions were collected for 7 days after vaccination. The majority of solicited reactions were reported as mild or moderate in intensity and resolved within 3 days.

Commonly reported (≥10%) adverse reactions in adults 50 to less than 65 years of age who received Fluad® Quad were injection site pain (47.1%), fatigue (29.5%), headache (22.2%), arthralgia (13.7%) and myalgia (13.0%).

The frequency of all solicited local and systemic adverse reactions reported in Study V118_23 is presented in Table 1.

Table 1: Incidence of Solicited Adverse Reactions[a] Reported in the Solicited Safety Population[b] Reported within 7 Days of Vaccination (Study V118_23)

	Percentage (%) of Subjects Reporting a Solicited Reaction			
	Fluad® Quad N=1020		Comparator QIV N=1008	
Local (Injection site) Reactions				
	Any[c]	**Severe[d]**	**Any[c]**	**Severe[d]**
Injection site pain	47.1	0.1	28.1	0.3
Induration	7.9	0.1	3.5	0.0
Erythema	7.8	0.4	3.1	0.0
Ecchymosis	0.6	0.0	0.6	0.0
Systemic Reactions				
Fatigue	29.5	0.7	24.3	1.0
Headache	22.2	0.0	20.4	0.5
Arthralgia	13.7	0.4	9.4	0.6
Myalgia	13.0	0.4	7.2	0.4
Diarrhoea	7.9	0.0	7.0	0.2
Nausea	7.3	0.1	4.4	0.0
Chills	6.6	0.1	5.5	0.3
Loss of appetite	6.1	0.2	4.8	0.4
Fever	2.5	0.8	1.7	0.4
Vomiting	0.3	0.0	1.0	0.0

Abbreviation: N=number of subjects with solicited safety data

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

[b] Solicited Safety Population: all subjects in the exposed population who provided post-vaccination solicited safety data

[c] Any definitions: Erythema, Induration and Ecchymosis = ≥25 mm diameter, Fever = ≥ 38°C

[d] Severe definitions: Erythema, Induration and Ecchymosis = > 100 mm diameter; Injection site pain, Nausea, Fatigue, Myalgia, Arthralgia, Headache, and Chills = prevents daily activity; 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; Fever = ≥ 39°C.

Unsolicited Adverse Events (AEs) were collected for 21 days after vaccination. There were no individual unsolicited adverse reactions reported as possibly or probably related in ≥1% of subjects who received Fluad® Quad.

Serious adverse events (SAEs), AEs leading to withdrawal and adverse events of special interest (AESIs) were collected up to Day 271. There were no SAEs, AEs leading to withdrawal, AESIs or deaths in this study that were related to Fluad® Quad.

Elderly population 65 years of age and older

The safety of a single dose of Fluad® Quad in subjects 65 years of age and older was evaluated in clinical study V118_20. Refer to section **5.1 – PHARMACODYNAMIC PROPERTIES** for further details.

In study V118_20, adverse events were collected as either solicited or unsolicited AEs. Solicited local and systemic events were collected for 7 days after vaccination (Table 2). Unsolicited AEs were collected for 21 days following vaccination, and for the full duration of study participation for SAEs, AEs leading to withdrawal from the study, new onset of chronic diseases (NOCDs), and AESIs.

In the study, 51.8% of subjects reported any solicited AE after Fluad® Quad vaccination, compared with 48.7%, and 48.2 % in the Fluad® and aTIV-2 groups respectively. The most commonly reported (≥10%) solicited AEs were injection site pain (31.9%), fatigue (16%) and headache (12.0%) (see Table 2). The majority of the adverse events reported were mild or moderate in intensity and resolved within 3 days. Solicited AEs with severe intensity were uncommon in all study groups.

Overall, the solicited AEs show that the safety profile of Fluad® Quad in subjects 65 years of age and older was generally similar compared to the aTIV comparators.

Table 2: Incidence of Solicited Local and Systemic Adverse Events[a] in the Solicited Safety Population[b] Reported within 7 Days After Dosing (Study V118_20)

	Percentage (%) of Subjects Reporting a Solicited Event					
	Fluad® Quad N=883		**Fluad® N=439**		**aTIV-2 N=438**	
Local (Injection site) Reactions						
	Any[c]	**Severe[d]**	**Any[c]**	**Severe[d]**	**Any[c]**	**Severe[d]**
Injection site pain	31.9	0.0	29.1	0.9	25.7	0.2
Erythema	7.6	0.0	7.4	0.3	8.6	0.0
Induration	7.0	0.0	5.4	0.0	5.3	0.0
Ecchymosis	2.5	0.1	1.5	0.0	1.5	0.0

Systemic Reactions						
Fatigue	16.0	0.7	15.4	0.7	11.5	1.4
Headache	12.0	0.5	10.6	0.7	11.3	0.7
Arthralgia	9.1	0.3	8.5	0.0	7.1	1.2
Myalgia	8.1	0.5	7.8	0.0	6.9	0.9
Diarrhoea	5.5	0.6	5.5	0.5	6.9	0.7
Chills	4.7	0.2	3.4	0.5	4.4	0.7
Nausea	4.0	0.2	4.1	0.0	4.6	0.9
Loss of appetite	3.2	0.2	4.8	0.0	3.7	0.5
Vomiting	0.8	0.1	0.5	0.0	2.1	0.7
Fever	0.5	0.1	0.2	0.0	0.5	0.0

Abbreviation: N=number of subjects with solicited safety data;

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

[b] Solicited Safety Population: all subjects in the exposed population who provided post-vaccination solicited safety data

[c] "Any" definitions: Erythema, Induration and Ecchymosis = ≥ 25 mm diameter, fever = ≥ 38°C;

[d] "Severe" definitions: Erythema, Induration and Ecchymosis >100 mm diameter; injection site pain, nausea, fatigue, myalgia, arthralgia, headache, and chills = prevents daily activity; 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; Fever = ≥ 39°C.

Unsolicited Adverse Events (AEs) were collected for 21 days after vaccination. The frequency of unsolicited AEs was similar between the different vaccination groups, Fluad® Quad (15.3%), Fluad® (11.3%) and aTIV-2 (15.3%). Influenza-like-illness (2.0%), injection site bruising (1.1%) and cough (1.0%) were reported in ≥1% of subjects who received Fluad® Quad.

No treatment-related SAE or death were reported in the study.

Two AESIs were reported during the study: one in the Fluad® group, and one in the Fluad® Quad group. Neither of the AESIs was considered to be related to study vaccine.

The frequency of unsolicited events leading to NOCD was similar across study groups: Fluad® Quad (2.6%); Fluad® (3.6%) and aTIV-2 (3.2%). NOCDs were heterogeneous in nature and consistent with the clinical conditions spontaneously occurring in subjects 65 years of age and older. No reported NOCDs were considered related to study vaccine.

No unsolicited AEs led to withdrawal from the study.

Post-marketing surveillance

In addition to the adverse reactions observed during clinical trials, the following adverse events were reported from post-marketing surveillance for Fluad® Quad or for Fluad®,

which is relevant because both vaccines are manufactured using the same process and have overlapping compositions.

As these events were reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or to establish, for all events, a causal relationship to vaccine exposure.

Blood and lymphatic system disorders

Thrombocytopenia (some very rare cases were severe with platelet counts less than 5,000 per mm^3), lymphadenopathy.

General disorders and administration site conditions

Extensive swelling of injected limb, injection site swelling, peripheral swelling, injection-site cellulitis-like reaction, asthenia, malaise, pyrexia.

Immune system disorders

Allergic or immediate hypersensitivity reactions, including anaphylactic shock (in rare cases), anaphylaxis.

Musculoskeletal and connective tissue disorders

Muscular weakness, pain in extremity.

Nervous system disorders

Encephalomyelitis, Guillain-Barré Syndrome, convulsions, neuritis, neuralgia, paraesthesia, syncope, presyncope, dizziness.

Skin and subcutaneous tissue disorders

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

Vascular disorders

Vasculitis which may be associated with transient renal involvement.

Reporting of 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 via https://pophealth.my.site.com/carmreportnz/s/.

4.9 OVERDOSE

There are no data on overdose with Fluad®.

For risk assessment and advice on the management of overdose, contact the New Zealand Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Pharmacotherapeutic group: Influenza Vaccines

ATC Code: J07BB02

Mechanism of action

Fluad® provides active immunisation against three influenza virus strains (two A subtypes and one B type) contained in the vaccine.

Fluad® has been shown to evoke antibody responses to the viral surface glycoproteins, haemagglutinin and neuraminidase. These antibodies provide protection against clinical illness in a high proportion of vaccine recipients.

The antibody response to Fluad® Quad is similar to Fluad® which is increased when compared to the response to vaccines without adjuvant and is most pronounced for A/H3N2 influenza antigens. This increased response is even more pronounced in subjects 65 years of age and older.

The adjuvant MF59 broadens the overall immune response allowing the vaccine to offer greater protection against heterologous strains of the virus. This may be important when there is a mismatch between the virus strains included in the vaccine and the strains circulating in the community. The antibody response is increased when compared to the response to non-adjuvanted Inactivated Influenza Vaccine. This increased response is seen particularly in elderly subjects with low pre-immunisation titres and/or with underlying diseases (diabetes, cardiovascular and respiratory diseases) who are at increased risk of complications of influenza infection.

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 in adults, antibody titres of 1:40 or greater have been associated with protection from influenza illness in up to 50% of subjects.

Antibody against a specific influenza virus type or subtype confers limited or no protection against another. Furthermore, antibody to a specific antigenic variant of influenza virus might not protect against a new antigenic variant of the same type or subtype.

The addition of the squalene-based MF59 oil-in-water emulsion adjuvant in Fluad® leads to enhanced antigen uptake by recruiting immune cells at the injection site and differentiating into antigen presenting cells. This results in an increased magnitude, breadth and persistence of the immune response through the duration of the influenza season compared with non-adjuvanted influenza vaccines.

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

Clinical trials

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

Immunogenicity

Adults 50 to less than 65 years of age

Immunogenicity of Fluad® Quad in adults 50 to less than 65 years of age was evaluated in Study V118_23. This was a randomised, observer-blind, controlled, multi-centre, trial conducted in the US, Germany and Estonia, during the 2021-22 Northern Hemisphere season. In the study adults 50 to less than 65 years of age who were healthy or had comorbidities that increased their risk of hospitalisation for influenza-associated complications, were enrolled to receive one dose of either Fluad® Quad (N=1027) or a non-adjuvanted quadrivalent comparator influenza vaccine (Comparator QIV; Fluarix® Quadrivalent) (N=1017). The mean age of subjects enrolled in the Fluad® Quad group was 57.8 years and females represented 62% of subjects.

The primary endpoints to assess noninferiority were haemagglutination inhibition (HI) geometric mean antibody titre (GMT) and seroconversion rates (SCR) 21 days after vaccination. Fluad® Quad met the noninferiority criteria for all 4 strains (Table 3).

A superior immune response was assessed based on post-vaccination GMTs with a prespecified superiority criteria that the upper limit of the 95% CI for the inter-group

GMT ratio (Comparator QIV/FLUAD QIV) be <1. A/H1N1 and A/H3N2 met the superiority criteria. The B strains did not meet the pre-specified criteria for immunological superiority.

Table 3: Noninferiority of Fluad QIV Relative to Comparator QIV in Adults 50 to less than 65 Years of Age – Per-Protocol Analysis Set (PPS) (Study V118_23)

Strain	GMT (95% CI)		GMT Ratio	Met Pre-defined Noninferiority Criteria[a]
	FLUAD QIV N=983	Comparator QIV N=985	Comparator QIV/ FLUAD QIV (95% CI)	
A/H1N1	731.90 (689.39, 777.04)	586.85 (552.83, 622.96)	0.80 (0.74, 0.87)	Yes
A/H3N2	347.89 (324.78, 372.64)	313.16 (292.42, 335.36)	0.90 (0.82, 0.99)	Yes
B/Yamagata	154.40 (146.80, 162.40)	145.74 (138.57, 153.27)	0.94 (0.88, 1.01)	Yes
B/Victoria	144.41 (136.97, 152.26)	143.32 (135.97, 151.07)	0.99 (0.92, 1.07)	Yes
Strain	Seroconversion[b] rate (95% CI)		Seroconversion Difference	
	FLUAD QIV N=983	Comparator QIV N=985	Comparator QIV - FLUAD QIV (95% CI)	
A/H1N1	81.2% (78.57, 83.58)	76.8% (74.04, 79.42)	-4.4 (-7.97, -0.74)	Yes
A/H3N2	63.6% (60.46, 66.63)	61.8% (58.61, 64.82)	-1.8 (-6.14, 2.48)	Yes
B/Yamagata	43.4% (40.27, 46.60)	41.0% (37.92, 44.19)	-2.4 (-6.77, 2.00)	Yes
B/Victoria	44.5% (41.39, 47.74)	40.6% (37.52, 43.76)	-3.9 (-8.31, 0.45)	Yes

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

[a] Pre-specified noninferiority criteria required that the upper limit (UL) of the 95% CI of the GMT ratio of Comparator QIV/FLUAD QIV be ≤1.5, and that the UL of the 95% CI of the seroconversion rate difference (Comparator QIV minus FLUAD QIV) be ≤10% for all strains (Per Protocol Set)

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

Elderly population 65 years of age and older

The immunogenicity of Fluad® Quad was evaluated in clinical study V118_20, a multi-centre, randomised, double-blind, non-inferiority, comparator-controlled study conducted in subjects 65 years of age and older in the 2017-18 Northern Hemisphere influenza

season. In this study, 888 received Fluad® Quad, 444 subjects received the licensed trivalent influenza vaccine (Fluad®, aTIV-1) and 444 subjects received an adjuvanted trivalent influenza vaccine containing the alternative B strain (a-TIV-2).

The per protocol immunogenicity set included a total of 1741 subjects: Fluad® Quad (N=872), Fluad® (N=436) and aTIV-2 (N=433). In the per protocol set, the mean age of subjects at enrolment who received Fluad® Quad was 72.4 years.

Non-inferiority of the immune response of Fluad® Quad to that of Fluad® (aTIV-1) and TIV-2 among adults 65 years of age or older was assessed as a co-primary endpoint. Adjusted HI Geometric Mean Titre (GMT) ratios and the difference in seroconversion rates for each vaccine strain were assessed 21 days after vaccination. Pre-specified non-inferiority criteria required that the upper bound of the 2-sided 95% CI of the GMT ratio ($GMT_{aTIV}/GMT_{Fluad® Quad}$) did not exceed 1.5 and the upper bound of the 2-sided 95% CI of the seroconversion rate difference ($SCR_{aTIV}–SCR_{Fluad® Quad}$) did not exceed 10% for each strain.

Fluad® Quad was non-inferior for all 4 influenza strains for both HI antibody titres and seroconversion rates (Table 4).

Table 4: Comparison of Immune Responses to Each Antigen 21 days After Vaccination with Fluad® Quad and Adjuvanted Trivalent Comparator Vaccines in Subjects 65 years of Age and Older (per protocol set)

	GMT (95% CI)			**GMT Ratio**	**Met predefined non-inferiority criteria?[a]**
Strain	**Fluad® Quad N=872**	**Fluad® (B-Victoria) N=436**	**aTIV-2 (B-Yamagata) N=433**	**aTIV[d]/Fluad® Quad (95% CI)**	
A/H1N1	65.01 (57.79; 73.13)	75.16 (66.68; 84.72)		1.16 (1.05; 1.27)	Yes
A/H3N2	294.91 (261.88; 332.09)	293.31 (259.91; 330.99)		0.99 (0.90; 1.09)	Yes
B/Yamagata	24.67 (22.67; 26.84)	NA	24.30 (22.0; 26.84)	0.99 (0.90; 1.08)	Yes
B/Victoria	30.78 (28.27; 33.51)	30.13 (27.31; 33.24)	NA	0.98 (0.89; 1.08)	Yes

	Seroconversion %[c] (95% CI)			Seroconversion Difference	Met predefined non-inferiority criteria?[b]
Strain	**Fluad® Quad N=872**	**aTIV-1 (B-Victoria) N=436**	**aTIV-2 (B-Yamagata) N=433**	**aTIV[d]- Fluad® Quad (95% CI) (95% CI) aTIV**	
A/H1N1	35.21 (32; 38.5)	39.45 (34.8; 44.2)	37.41 (32.8; 4.2)	3.23 (-1.30, 7.76)	Yes
A/H3N2	39.33 (36.1; 42.7)	39.70 (36.4; 43.0)	37.18 (32.6; 41.9)	0.37 (-4.23, 4.96)	Yes
B/Yamagata	16.4 (14.0; 19.0)	NA	15.47 (12.2;19.2)	-0.93 (-5.13; 3.27)	Yes
B/Victoria	13.42 (11.2; 15.9)	12.16 (9.24; 15.6)	NA	-1.26 (-5.07; 2.55)	Yes

Abbreviations: GMT= Geometric Mean antibody Titre; CI= Confidence Interval; NA= Not Applicable.
N=the number of vaccinated subjects with available data from the immunogenicity endpoint listed (Per Protocol Set).

[a] Non-inferiority for the GMT ratio was defined as: the upper bound of the two-sided 95% CI for the ratio of the GMTs did not exceed 1.5.

[b] Non-inferiority for the seroconversion difference was defined as: the upper bound of the two-sided 95% CI for the difference between the seroconversions did not exceed 10%.

[c] Seroconversion was defined as pre-vaccination HI titre <1:10 and post-vaccination HI titre ≥ 1:40 or at least a 4-fold increase in HI from pre-vaccination HI titre ≥ 1:10.

[d] aTIV-1 and aTIV-2 vaccine groups are pooled for the analysis of A/H1N1 and A/H3N2 strains. For B/Victoria aTIV=aTIV-1, for B/Yamagata aTIV=aTIV-2.

Immunogenicity based on CBER (Center for Biologics Evaluation and Research) criteria as measured by the percentage of subjects achieving seroconversion for HI antibodies and percentage of subjects achieving an HI antibody titre ≥1:40 at 21 days post-vaccination was assessed as a second co-primary endpoint. Success criteria was met if the lower limit of the two-sided 95% CI for the percentage of subjects achieving seroconversion for HI antibody met or exceeded 30% and the lower limit of the two-sided 95% CI for the percentage of subjects achieving an HI antibody titre ≥1:40 met and exceeded 60%.

The second co-primary objective was met for A strains (H1N1 and H3N2), but not for B strains (B-Yamagata and B-Victoria). Results for B strains in the Fluad® and aTIV-2 groups were similar to those obtained for Fluad® Quad.

5.2 PHARMACOKINETIC PROPERTIES

Not applicable.

5.3 PRECLINICAL SAFETY DATA

Nonclinical data reveal no special hazard for humans based on conventional studies of repeated-dose toxicity (60 mcg HA/dose), local tolerance and sensitization (45 mcg HA/dose). For the reproductive and development toxicity refer to section **4.6 – FERTILITY, PREGNANCY AND LACTATION**.

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Each 0.5 mL dose of Fluad® contains MF59C.1 (a proprietary adjuvant): containing squalene (of fish origin) 9.75 mg, polysorbate 80 1.175 mg, sorbitan trioleate 1.175 mg, sodium citrate dihydrate 0.66 mg, citric acid monohydrate 0.04 mg and water for injections and the following excipients.

Sodium chloride	4.00 mg
Potassium chloride	0.10 mg
Monobasic potassium phosphate	0.10 mg
Dibasic sodium phosphate dihydrate	0.67 mg
Magnesium chloride hexahydrate	0.05 mg
Calcium chloride dihydrate	0.06 mg
Water for injections	up to 0.5 mL

Fluad® contains no antimicrobial preservative.

6.2 INCOMPATIBILITIES

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

6.3 SHELF LIFE

12 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

Fluad®, inactivated, trivalent influenza vaccine (surface antigen), adjuvanted, suspension for injection, 0.5 mL pre-filled syringe, needle-free is a 0.5 mL suspension for injection in a needle-free pre-filled syringe (type I glass).

The syringe barrel, plunger and rubber stopper are not manufactured with natural rubber latex.

Pack sizes: 1's; 10's.

Pre-filled syringe – attached needle

Fluad®, inactivated, trivalent influenza vaccine (surface antigen), adjuvanted, suspension for injection, 0.5 mL pre-filled syringe, with attached needle is a 0.5 mL suspension for injection in a pre-filled syringe (type I glass) with attached needle.

The sheath covering the needle contains natural rubber latex, refer to statement on carton (see **Section 4.4 – SPECIAL WARNINGS AND PRECAUTIONS FOR USE**).

The syringe barrel, plunger and rubber stopper are not manufactured with natural rubber latex.

Pack sizes: 1's; 10's.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

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

7 MEDICINE SCHEDULE

Prescription medicine

8 SPONSOR

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

9 DATE OF FIRST APPROVAL

16 January 2020

10 DATE OF REVISION

06 October 2025

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
2	Season and strain information updated.
4.4, 6.5	Minor editorial changes.