NEW ZEALAND DATA SHEET

FLUAD® 0.5 mL Suspension for injection

1. PRODUCT NAME

FLUAD®, suspension for injection in pre-filled syringe
Influenza Vaccine, Surface Antigen, Inactivated, Adjuvanted with MF59C.1
(2019 SEASON)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.5 mL dose of FLUAD® contains inactivated influenza virus surface antigens of the strains*:

A/Michigan/45/2015 (H1N1) pdm09 – like strain (A/Singapore/GP1908/2015 (IVR-180))
15 micrograms HA**

A/Switzerland/8060/2017 (H3N2) – like strain (A/Brisbane/1/2018 (X-311))
15 micrograms HA**

B/Phuket/3073/2013 - like strain (B/Phuket/3073/2013 (BVR-1B))
15 micrograms HA**

*propagated in eggs and adjuvanted with MF59C.1
**haemagglutinin

Adjuvant: MF59C.1 (a proprietary adjuvant): 9.75 mg squalene, 1.175 mg polysorbate 80, 1.175 mg sorbitan trioleate, 0.66 mg sodium citrate dihydrate, 0.04 mg citric acid monohydrate, water for injection.

Fluad® may also contain kanamycin sulfate, neomycin sulfate, formaldehyde, chicken proteins (e.g. ovalbumin), cetyltrimethylammonium bromide (CTAB), sucrose, barium sulfate and hydrocortisone as residues of the manufacturing process.This vaccine complies with the World Health Organisation (WHO) and New Zealand Ministry of Health recommendations for the 2019 Southern Hemisphere Influenza season

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection in pre-filled syringe.

The vaccine appears as a milky-white suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Active immunisation against influenza in the elderly (65 years of age and older), especially for those with an increased risk of associated complications (i.e. patients affected by underlying chronic diseases including diabetes, cardiovascular and respiratory diseases).

The use of FLUAD® should be based on official recommendations.

4.2 Dose and method of administration

Dose

Adults 65 years and older: single 0.5 mL dose.

Annual vaccination is recommended.

Method of administration

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

Visually inspect the contents of each FLUAD® pre-filled syringe for particulate matter or discoloration prior to administration. If either condition is observed, do not use the contents.

The vaccine should be administered by intramuscular injection into the deltoid muscle.
Due to the presence of the adjuvant, the injection should be carried out by using a 1 inch needle.

4.3 Contraindications

Hypersensitivity to the active substances, components of the adjuvant, any of the excipients listed in section 6.1, or residues (e.g. eggs, chicken proteins (e.g. ovalbumin), kanamycin sulfate and neomycin sulfate, formaldehyde , cetyltrimethylammonium bromide (CTAB), barium sulfate and hydrocortisone) or anyone who has had an anaphylactic reaction to previous influenza vaccination.

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

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.

FLUAD® should under no circumstances be administered intravascularly or subcutaneously.

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

A protective response may not be elicited in all vaccinees.

The syringe is for single use only and should not be used in more than one person.

The syringe and all associated syringe components for Fluad® prefilled syringe without needle 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. See **Section 6.5 - Nature and contents of container** for further information.

4.5 Interaction with other medicinal products and other forms of interaction

FLUAD® may be given at the same time as other vaccines although no clinical data on concomitant administration with other vaccines are available. 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.

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 results. The transient false positive reactions could be due to the IgM response by the vaccine.

4.6 Fertility, pregnancy and lactation

Not applicable.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

A higher incidence of mild post-immunisation reactions has been reported with FLUAD® compared to non-adjuvanted influenza vaccines.

Adverse reactions observed from clinical trials

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

Very common (≥ 1/10); common (≥ 1/100, < 1/10); uncommon (≥ 1/1,000, < 1/100); rare (≥ 1/10,000, < 1/1,000); very rare (< 1/10,000), including isolated reports.

Nervous system disorders
Common (≥ 1/100, < 1/10): Headache*

Skin and subcutaneous tissue disorders
Common (≥ 1/100, < 1/10): Sweating*

Musculoskeletal and connective tissue disorders
Common (≥ 1/100, < 1/10): Myalgia, arthralgia*

General disorders and administration site conditions
Common (≥ 1/100, < 1/10): Fever, malaise, shivering, fatigue.
Local reactions: redness, swelling, pain at injection site, ecchymosis, induration.*

*These reactions usually disappear within 1-2 days without treatment.

Adverse reactions from spontaneous reporting

Because 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. In addition to the adverse reactions observed during clinical trials, the following adverse reactions were reported from post marketing surveillance in subjects older than 65 years of age:

Blood and lymphatic system disorders
Thrombocytopenia (some very rare cases were severe with platelet counts less than 5,000 per mm3), lymphadenopathy.

Immune system disorders
Allergic reactions including anaphylactic shock (in rare cases), anaphylaxis, and angioedema.

Nervous system disorders
Encephalomyelitis , Guillain Barrè syndrome, neuritis,neuralgia, paraesthesia, convulsions
Vascular disorders
Vasculitis with transient renal involvement.

Skin and subcutaneous tissue disorders
Generalised skin reactions including erythema multiforme, pruritus, urticaria or non-specific rash.

Musculoskeletal and connective tissue disorders
Muscular weakness

General disorders and administration site conditions
Extensive swelling of injected limb lasting more than one week, injection-site cellulitis-like reaction (some cases of swelling, pain, and redness extending more than 10 cm and lasting more than 1 week).

Reporting 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 using the following website:
https://nzphvc.otago.ac.nz/reporting/

4.9 Overdose

Overdosage is unlikely to have any untoward effect.

For general advice on overdose management please contact the New Zealand Poisons Centre on 0800 POISON or 0800 764 766.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Influenza vaccine, ATC code: J07BB02

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

Although comparative field efficacy trials have not been performed, the antibody response to FLUAD® is increased when compared to the response to vaccines without adjuvant, and is most pronounced for B and A/H3N2 influenza antigens.

This increased response is seen particularly in elderly subjects with low pre-immunisation titre and/or with underlying diseases (diabetes and cardiovascular and respiratory diseases) who are at increased risk of complications of influenza infection. A similar immunogenicity profile has been noted after a second and third immunisation with FLUAD®.

Significant antibody rises after immunisation with FLUAD® have also been shown against heterovariant strains, antigenically different from those included in the vaccine.

Influenza viral strains undergo antigenic changes from year to year. Therefore the antigen component of FLUAD® is revised for every flu season and annual vaccination is recommended.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of repeated-dose toxicity, genotoxicity and local tolerance.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Adjuvant: see section 2.

Other:
- sodium chloride
- potassium chloride
- monobasic potassium phosphate
- dibasic sodium phosphate dihydrate
- magnesium chloride hexahydrate
- calcium chloride dihydrate, and
- water for injections.

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

6.4 Special precautions for storage

Store in a refrigerator (2°C - 8°C). Do not freeze. Keep the syringe in the outer carton in order to protect from light.

6.5 Nature and contents of container

Not all presentations or pack sizes may be marketed.

0.5 mL of suspension in pre-filled syringe (type I glass), presented with or without needle, pack of 1 or 10.

Fluad® in a pre-filled syringe (type I glass) with attached needle

The sheath covering the needle contains natural rubber latex (see **Section 4.4 - Special warnings and precautions for use**).
The syringe barrel, plunger and rubber stopper are not manufactured with natural rubber latex.

Fluad® in a pre-filled syringe (type I glass) without needle

The syringe and all associated syringe components do not contain natural rubber latex.

6.6 Special precautions for disposal and other handling

Any unused product 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

10 January 2020

10. DATE OF REVISION OF THE TEXT

Not applicable

SUMMARY OF CHANGES

Section Changed	Summary of new information
4.2	Instruction to warm vaccine before use removed
4.4 and 6.5	Latex information added
6.1	Ingredient names updated
2	Influenza strains updated for Southern Hemisphere 2019 Season