

NEW ZEALAND DATA SHEET

FLUAD[®] 0.5mL Suspension for injection

NAME OF THE MEDICINAL PRODUCT

Fluad, suspension for injection in pre-filled syringe
Influenza Vaccine, Surface Antigen, Inactivated, Adjuvanted with MF59C.1
(2011/2012 SEASON)

QUALITATIVE AND QUANTITATIVE COMPOSITION

Influenza virus surface antigens (haemagglutinin and neuraminidase), of strains*:

A/California/7/2009 (H1N1) - derived strain used NYMC X-181
15 micrograms HA**

A/Perth/16/2009 (H3N2) - like strain used NYMC X-187 derived from A/Victoria/210/2009
15 micrograms HA**

B/Brisbane/60/2008 - derived strain used NYMC BX-35
15 micrograms HA**

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

Adjuvant: MF59C.1 which is an exclusive adjuvant (Patent EP 0 399 843 B1): 9.75 mg squalene, 1.175 mg polysorbate 80, 1.175 mg sorbitan trioleate, 0.66 mg sodium citrate, 0.04 mg citric acid, water for injection.

For one dose of 0.5 ml

This vaccine complies with the WHO recommendations (Northern Hemisphere) and EU decision for the 2011/2012 season.

For a full list of excipients, see section 6.1.

PHARMACEUTICAL FORM

Suspension for injection in pre-filled syringe.

The vaccine appears as a milky-white suspension.

CLINICAL PARTICULARS

Therapeutic indications

Active immunisation against influenza in the elderly (65 years of age and over), 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.

Posology and method of administration

A single 0.5 ml dose 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.

For instructions for preparation, see section 6.6.

Contraindications

Hypersensitivity to the active substances, to any of the excipients and to eggs, chicken proteins, e.g. such as ovoalbumin, kanamycin and neomycin sulphate, formaldehyde and cetyltrimethylammonium bromide (CTAB).

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

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.

Interaction with other medicinal products and other forms of interaction

FLUAD may be 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.

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.

Fertility, pregnancy and lactation

Not applicable.

Effects on ability to drive and use machines

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

Undesirable effects

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

Adverse reactions observed from clinical trials

The safety of Fludac is assessed in open label, uncontrolled clinical trials performed as an annual update requirement, including at least 50 elderly aged 65 years or older. Safety evaluation is performed during the first 3 days following vaccination.

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

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

Nervous system disorders

Common ($\geq 1/100$, $< 1/10$): Headache*

Skin and subcutaneous tissue disorders

Common ($\geq 1/100$, $< 1/10$): Sweating*

Musculoskeletal and connective tissue disorders

Common ($\geq 1/100$, $< 1/10$): Myalgia, arthralgia*

General disorders and administration site conditions

Common ($\geq 1/100$, $< 1/10$): 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 reported from post-marketing surveillance

Adverse reactions reported from post marketing surveillance are, next to the reactions which have also been observed during the clinical trials, the following:

Blood and lymphatic system disorders

Transient thrombocytopenia, lymphadenopathy.

Immune system disorders

Allergic reactions, in rare cases leading to shock, have been reported.

Nervous system disorders

Neuralgia, paraesthesia, convulsions

Neurological disorders such as encephalomyelitis, neuritis and Guillain Barré syndrome.

Vascular disorders

Vasculitis with transient renal involvement and exudative erythema multiforme.

Skin and subcutaneous tissue disorders

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

Musculoskeletal and connective tissue disorders

pain in the extremity, muscular weakness

General disorders and administration site conditions

Asthenia, Influenza-Like Illness (ILI)

Overdose

Overdosage is unlikely to have any untoward effect.

PHARMACOLOGICAL PROPERTIES

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.

Pharmacokinetic properties

Not applicable.

Preclinical safety data

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

PHARMACEUTICAL PARTICULARS

List of excipients

Adjuvant: see section 2.

Other: sodium chloride, potassium chloride, potassium dihydrogen phosphate, disodium phosphate dihydrate, magnesium chloride hexahydrate, calcium chloride dihydrate and water for injections.

Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

Shelf life

1 year

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.

Nature and contents of container

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

Pack of 1, with or without needle.
Pack of 10x, with or without needle.

Not all pack sizes may be marketed.

Special precautions for disposal and other handling

The vaccine should be allowed to reach room temperature before use. Gently shake before use.

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

MEDICINE CLASSIFICATION

Prescription Medicine

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DATE OF PREPARATION

4 November 2011