AUSTRALIAN PRODUCT INFORMATION

NAME OF THE MEDICINE

Fluzone High-Dose

Inactivated Trivalent Influenza Vaccine (Split Virion)

DESCRIPTION

Fluzone High-Dose for intramuscular injection is an inactivated influenza virus vaccine. It contains 180 micrograms (µg) haemagglutinin (HA) per 0.5 mL dose in the recommended ratio of 60 µg HA of each of the three strains recommended for the 2018 influenza season:

- A/Michigan/45/2015 (H1N1) pdm09-like virus (A/Michigan/45/2015 X-275)
- A/Singapore/INFIMH-16-0019/2016 (H3N2)-like virus (A/Singapore/INFIMH-16-0019/2016 NIB-104)
- B/Phuket/3073/2013-like virus (B/Phuket/3073/2013; Yamagata lineage)

The type and amount of viral antigens contained in Fluzone High-Dose conform to the annual requirements of the Australian Influenza Vaccine Committee (AIVC) and the World Health Organisation (WHO) recommendations for the season.

Fluzone High-Dose is prepared from influenza viruses propagated in embryonated chicken eggs and inactivated with formaldehyde. The influenza virus is concentrated and purified, and is then chemically disrupted to produce a "split virus". The split virus is further purified by ultrafiltration and diluted to appropriate concentration. Antigens from the three strains included in the vaccine are produced separately and then combined to make the trivalent formulation.

The ingredients per dose of vaccine are listed in Table 1.

Table 1 - Fluzone High-Dose Ingredients

Active Substance	Quantity (per 0.5 mL dose)	Excipients	Quantity (per 0.5 mL dose)
Influenza virus haemagglutinin[a]:	180 µg HA total	Sodium chloride	3.3 mg
A (H1N1)	60 µg HA	Dibasic sodium phosphate	1915 µg
A (H3N2)	60 µg HA	Monobasic sodium phosphate	205 µg
B	60 µg HA	Octoxinol-9	≤ 250 µg
		Water for injections	Up to 0.5 mL

Active Substance	Quantity (per 0.5 mL dose)	Excipients	Quantity (per 0.5 mL dose)

[a] per AIVC and WHO recommendations

Fluzone High-Dose may also contain traces of formaldehyde (≤ 100 µg) and ovalbumin (<1 µg). Neither antibiotics nor preservative are used during manufacture.

Fluzone High-Dose is presented in prefilled syringes that are not made with natural rubber latex.

Fluzone High-Dose suspension for injection is clear and slightly opalescent in colour.

PHARMACOLOGY

Mechanism of action

Fluzone High-Dose provides active immunisation against three influenza virus strains (two A subtypes and one B strain) contained in the vaccine. Fluzone High-Dose induces humoral antibodies against the haemagglutinins. Specific levels of haemagglutination inhibition (HI) antibody titre post-vaccination with inactivated influenza virus vaccines have not been correlated with protection from influenza virus infection. In some human studies, HI antibody titres of ≥ 1:40 have been associated with protection from influenza illness in up to 50% of participants. Antibodies against one influenza virus type or subtype confer limited or no protection against another. Furthermore, antibodies to one antigenic variant of influenza virus might not protect against a new antigenic variant of the same type or subtype. Frequent development of antigenic variants through antigenic drift is the virologic basis for seasonal epidemics and the reason for the usual change of one or more new strains in each year's influenza vaccine. Therefore, influenza vaccines are standardized to contain the haemagglutinins of influenza virus strains representing the influenza viruses likely to be circulating in the Southern Hemisphere during the influenza season.

CLINICAL TRIALS

Two multi-centre, double-blind trials were conducted: one to determine safety and immunogenicity and one to evaluate efficacy in a total of 35 826 participants.

Immunogenicity of Fluzone High-Dose in Adults 65 Years of Age and Older

FIM05 was a multi-center, double-blind trial conducted in the US in which adults 65 years of age and older were randomised to receive either Fluzone High-Dose or Fluzone®[1](2006-2007 formulation). The study compared the safety and immunogenicity of Fluzone High-Dose to those

[1] Fluzone is the US-licensed standard-dose TIV upon which manufacture of Fluzone High-Dose is based.

of Fluzone. For immunogenicity analyses, 2576 participants were randomised to Fluzone High-Dose and 1275 participants were randomised to Fluzone. Females accounted for 51.3% of participants in the Fluzone High-Dose group and 54.7% of participants in the Fluzone group. In both groups, the mean age was 72.9 years (ranged from 65 through 97 years in the Fluzone High-Dose group and 65 through 94 years in the Fluzone group); 35% of participants in the Fluzone High-Dose group and 36% of participants in the Fluzone group were 75 years of age or older. Most participants in the Fluzone High-Dose and Fluzone groups, respectively, were White (91.7% and 92.9%), followed by Hispanic (4.8% and 3.7%), and Black (2.7% and 2.7%).

The primary endpoints of the study were HI geometric mean titres (GMTs) and seroconversion rates 28 days after vaccination. Pre-specified statistical superiority criteria required that the lower limit (LL) of the 2-sided 95% confidence interval (CI) of the GMT ratio (Fluzone High-Dose /Fluzone) be greater than 1.50 for at least two of the strains, and if one strain failed, non-inferiority of that strain must be demonstrated (LL>0.67), and that the lower limit of the 2-sided 95% CI of the seroconversion rate difference (Fluzone High-Dose minus Fluzone) be greater than 10% for at least two of the strains, and if one strain failed, non-inferiority of that strain must be demonstrated (LL>-10%). As shown in Table 2, statistically superior HI GMTs and seroconversion rates after vaccination with Fluzone High-Dose compared to Fluzone were demonstrated for influenza A subtypes, A (H1N1) and A (H3N2), but not for influenza type B. For strain B, non-inferiority of Fluzone High-Dose compared to Fluzone was demonstrated for both the HI GMTs and seroconversion rates.

Table 2 - FIM05: Post-Vaccination HI Antibody GMTs and Seroconversion Rates and Analyses of Superiority of Fluzone High-Dose Relative to Fluzone, Adults 65 Years of Age and Older

Influenza Strain	GMT		GMT Ratio	Seroconversion %[a]		Difference	Met Both Pre-defined Superiority Criteria[c]
	Fluzone High-Dose N[b]= 2542-2544	Fluzone N[b]= 1252	Fluzone High-Dose over Fluzone (95% CI)	Fluzone High-Dose N[b]= 2529-2531	Fluzone N[b]= 1248-1249	Fluzone High-Dose minus Fluzone (95% CI)	
A (H1N1)	115.8	67.3	1.7 (1.6; 1.8)	48.6	23.1	25.4 (22.4; 28.5)	Yes
A (H3N2)	608.9	332.5	1.8 (1.7; 2.0)	69.1	50.7	18.4 (15.1; 21.7)	Yes
B	69.1	52.3	1.3 (1.2; 1.4)	41.8	29.9	11.8 (8.6; 15.0)	No

[a] Seroconversion: Paired samples with pre-vaccination HI titre <1:10 and post-vaccination (day 28) titre ≥1:40 or a minimum 4-fold increase for participants with pre-vaccination titre ≥1:10

[b] N is the number of vaccinated participants with available data for the immunologic endpoint listed

[c] Predefined superiority criterion for seroconversion: the lower limit of the two-sided 95% CI of the difference of the seroconversion rates (Fluzone High-Dose minus Fluzone) is >10%. Predefined superiority criterion for the GMT ratio: the lower limit of the 95% CI of the GMT ratio (Fluzone High-Dose divided by Fluzone) is >1.5

Secondary Immunogenicity Objective: Seroprotection

The secondary immunogenicity objective was to describe the seroprotection of Fluzone High-Dose (based on the pooled responses elicited by the three lots) compared to that of Fluzone vaccine, where seroprotection was defined as an anti-hemagglutinin antibody titer ≥1:40. The percentage of subjects who had a titer of ≥1:40 at baseline were comparable for both groups for all three strains.

For the A (H1N1) strain, seroprotection was achieved by 89.9% of subjects in the Fluzone High-Dose group compared with 76.8% of subjects in the Fluzone vaccine group (difference between groups of 13.14%); for A (H3N2), seroprotection was achieved by 99.3% compared with 96.5%, respectively (difference of 2.81%); and for B, the values were 79.3% compared with 67.6%, respectively (difference of 11.70%).

Table 3 - Geometric Mean Titres 28 Days Post-Vaccination (Immunogenicity Analysis Set)[a]

	Fluzone High-Dose N[b] = 2576		Fluzone N[b] = 1275	
Influenza Strain	Mc	GMT (95% CI)	Mc	GMT (95% CI)
A(H1N1)	2543	115.79 (111.41; 120.34)	1252	67.29 (63.65; 71.13)
A(H3N2)	2544	608.87 (583.54; 635.30)	1252	332.46(310.44; 356.05)
B	2542	69.06 (66.60; 71.60)	1252	52.34 (49.48; 55.35)

[a]Immunogenicity analysis set: subjects who participated in immunogenicity assessments
[b]N is the number of participants in the immunogenicity analysis set
[c]M is the number of participants with a valid serology result for the strain, including results reported as less than the lower limit of quantification

Table 4 - Percentage of Subjects Achieving Seroprotection[a] at 28 Days Post-Vaccination (Immunogenicity Analysis Set)[b]

	Fluzone High-Dose N[c] = 2576		Fluzone N[c] = 1275		Fluzone High-Dose minus Fluzone
Influenza Strain	n[d]/M[e]	% ≥1:40 (95% CI)	n[d]/M[e]	% ≥1:40 (95% CI)	% (95% CI)
A (H1N1)	2286/2543	89.9 (88.66; 91.04)	961/1252	76.8 (74.32; 79.07)	13.14 (10.52; 15.75)
A (H3N2)	2526/2544	99.3 (99.88; 99.58)	1208/1252	96.5 (95.31; 97.44)	2.81 (1.74; 3.88)
B	2015/2542	79.3 (77.64; 80.83)	846/1252	67.6 (64.90; 70.16)	11.70 (8.66; 14.73)

	Fluzone High-Dose N[c] = 2576	Fluzone N[c] = 1275	Fluzone High-Dose minus Fluzone

[a]Seroprotection: HI Titers ≥1:40 at Day 28
[b]Immunogenicity analysis set: subjects who participated in immunogenicity assessments
[c]N is the number of participants in the immunogenicity analysis set
[d]n is the number of participants who achieved seroprotection for the strain
[e]M is the number of participants with a valid serology result for the strain, including results reported as less than the lower limit of quantification

Efficacy of Fluzone High-Dose in Adults 65 Years of Age and Older

FIM12 was a multi-center, double-blind efficacy trial conducted in the US and Canada in which adults 65 years of age and older were randomised (1:1) to receive either Fluzone High-Dose or Fluzone. The study was conducted over two influenza seasons (2011-2012 and 2012-2013) with a total of 31,989 participants randomised and vaccinated; 53% of participants enrolled in the first year of the study were re-enrolled and re-randomised in the second year. The per-protocol analysis set for efficacy assessments included 15,892 Fluzone High-Dose recipients and 15,911 Fluzone recipients. The majority (67%) of participants in the per-protocol analysis set for efficacy had one or more high-risk chronic comorbid conditions.

In the per-protocol analysis set, females accounted for 57.2% of participants in the Fluzone High-Dose group and 56.1% of participants in the Fluzone group. In both groups, the median age was 72.2 years (range 65 through 100 years). Overall, most participants in the study were White (95%); approximately 4% of study participants were Black, and approximately 6% reported Hispanic ethnicity.

The primary endpoint of the study was the occurrence of laboratory-confirmed influenza (as determined by culture or polymerase chain reaction) caused by any influenza viral type/subtype in association with influenza-like illness (ILI), defined as the occurrence of at least one of the following respiratory symptoms: sore throat, cough, sputum production, wheezing, or difficulty breathing; concurrent with at least one of the following systemic signs or symptoms: temperature >37.2°C, chills, tiredness, headaches or myalgia. Participants were monitored for the occurrence of a respiratory illness by both active and passive surveillance, starting 2 weeks post-vaccination for approximately 7 months. After an episode of respiratory illness, nasopharyngeal swab samples were collected for analysis; attack rates and vaccine efficacy were calculated (see Table 5).

Table 5 - FIM12: Relative Efficacy Against Laboratory-Confirmed Influenza[a] Regardless of Similarity to the Vaccine Components, Associated with Influenza-Like Illness[b], Adults 65 Years of Age and Older

	Fluzone High-Dose N[c]=15,892 n[d] (%)	Fluzone N[c]=15,911 n[d] (%)	Relative Efficacy % (95% CI)
Any type/subtype[e]	227 (1.43)	300 (1.89)	24.2 (9.7; 36.5)[f]
Influenza A	190 (1.20)	249 (1.56)	23.6 (7.4; 37.1)

	Fluzone High-Dose N[c]=15,892 n[d] (%)	Fluzone N[c]=15,911 n[d] (%)	Relative Efficacy % (95% CI)
A (H1N1)	8 (0.05)	9 (0.06)	11.0 (-159.9; 70.1)
A (H3N2)	171 (1.08)	222 (1.40)	22.9 (5.4; 37.2)
Influenza B[g]	37 (0.23)	51 (0.32)	27.4 (-13.1; 53.8)

[a] Laboratory-confirmed: culture- or polymerase-chain-reaction-confirmed
[b] Occurrence of at least one of the following respiratory symptoms: sore throat, cough, sputum production, wheezing, or difficulty breathing; concurrent with at least one of the following systemic signs or symptoms: temperature > 37.2°C, chills, tiredness, headaches or myalgia
[c] N is the number of vaccinated participants in the per-protocol analysis set for efficacy assessments
[d] n is the number of participants with protocol-defined influenza-like illness with laboratory confirmation
[e] Primary endpoint
[f] The pre-specified statistical superiority criterion for the primary endpoint (lower limit of the 2-sided 95% CI of the vaccine efficacy of Fluzone High-Dose relative to Fluzone > 9.1%) was met.
[g] In the first year of the study the influenza B component of the vaccine and the majority of influenza B cases were of the Victoria lineage; in the second year the influenza B component of the vaccine and the majority of influenza B cases were of the Yamagata lineage

A secondary endpoint of the study was the occurrence of culture-confirmed influenza caused by viral types/subtypes antigenically similar to those contained in the respective annual vaccine formulations in association with a modified CDC-defined ILI, defined as the occurrence of a temperature > 37.2°C with cough or sore throat. The efficacy of Fluzone High-Dose relative to Fluzone for this endpoint was 51.1% (95% CI: 16.8; 72.0).

INDICATIONS

Fluzone High-Dose is indicated for active immunisation against influenza disease caused by influenza virus types A and B contained in the vaccine for use in persons 65 years of age and older.

CONTRAINDICATIONS

Fluzone High-Dose should not be administered to anyone with a known systemic hypersensitivity reaction after previous administration of any influenza vaccine or to any component of the vaccine (e.g. egg or egg products) (see **DESCRIPTION**).

Fluzone High-Dose should be given in accordance with national recommendations as per the current Immunisation Handbook.

PRECAUTIONS

Do not administer intravenously.

Hypersensitivity

Prior to any vaccine injection, all known precautions should be taken to prevent hypersensitivity reactions. This includes a review of the individual's prior vaccination history with respect to possible hypersensitivity to the vaccine or similar vaccines. Adrenaline (epinephrine) injection (1:1000) and other appropriate agents used for the control of immediate allergic reactions must be available to treat unexpected reactions (e.g. anaphylaxis).

As each dose may contain traces of formaldehyde and octoxinol 9 which are used during vaccine production, caution should be exercised when the vaccine is administered to individuals with hypersensitivity to either one of these products.

Neurological Disorders

Recurrence of Guillain-Barré syndrome (GBS) has been temporally associated with the administration of influenza vaccine. Fluzone High-Dose should be administered to individuals who have a prior history of Guillain-Barré syndrome only based on careful consideration of the potential benefits and risks.

Immunisation should be delayed in a patient with an active neurological disorder, but should be considered when the disease process has stabilized.

Immunosuppressive Treatments or Conditions

The immunogenicity of Fluzone High-Dose may be reduced by immunosuppressive treatment or in individuals with immune deficiency syndromes. In such cases it is recommended to postpone the vaccination until after the immunosuppressive treatment or resolution of the immunosuppressive condition, if feasible.

Febrile or Acute Disease

Vaccination should be postponed in case of an acute or febrile disease, but a disease with low-grade fever is usually not a reason to postpone vaccination.

Protection

As with any vaccine, vaccination with Fluzone High-Dose may not protect 100% of recepients.

Influenza virus is remarkably unpredictable in that significant antigenic changes may occur from time to time. It is known that influenza vaccines, as now constituted, are not effective against all possible strains of influenza virus. Protection is limited to those strains of virus from which the vaccine is prepared or to closely related strains.

Bleeding disorder

Because any intramuscular injection can cause an injection-site haematoma in individuals with any bleeding disorder, such as haemophilia or thrombocytopaenia, or in individuals on anticoagulant therapy, intramuscular injections with Fluzone High-Dose should not be administered to such individuals unless the potential benefits outweigh the risk of administration. If the decision is made to administer any product by intramuscular injection to such individuals, it should be given with caution, with steps taken to avoid the risk of haematoma formation following injection.

Effects on Fertility

Fluzone High-Dose has not been evaluated for possible effects on human fertility.

Use in Pregnancy (Category C)

Animal reproduction studies have not been conducted with Fluzone High-Dose. It is also not known whether Fluzone High-Dose can cause foetal harm when administered to a pregnant woman or can affect reproduction capacity.

Fluzone High-Dose should not be given to a pregnant woman unless the potential benefits outweigh the risks.

Use in Lactation

It is not known whether Fluzone High-Dose is excreted in human milk hence, caution should be used when administering the vaccine to breastfeeding women.

Paediatric Use

Safety and effectiveness of Fluzone High-Dose in persons <65 years of age have not been established.

Use in the elderly

Fluzone High-Dose is intended for adults 65 years of age and over (See **CLINICAL TRIALS**).

Genotoxicity

Fluzone High-Dose has not been tested for genotoxic potential.

Carcinogenicity

Fluzone High-Dose has not been tested for carcinogenic potential.

Effect on Laboratory Tests

Interference of Fluzone High-Dose with laboratory and/or diagnostic tests has not been studied.

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. An appropriate Western Blot test should be used to confirm or disprove the results of the ELISA test. The transient false-positive reactions could be due to a non-specific IgM response induced by the vaccine.

INTERACTIONS WITH OTHER MEDICINES

Fluzone High-Dose should not be mixed with any other vaccine in the same syringe or vial.

There are no data to assess the concomitant administration of Fluzone High-Dose with other vaccines.

If Fluzone High-Dose is to be given at the same time as another injectable vaccine, the vaccines should always be administered at different injection sites.

If the vaccine is used in individuals deficient in producing antibodies due to immunosuppressive therapy, the expected immune response may not be obtained.

ADVERSE EFFECTS

Clinical Trials Experience

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.

Two clinical studies have evaluated the safety of Fluzone High-Dose.

FIM05 was a multi-centre, double-blind trial conducted in the US. In this study, adults 65 years of age and older were randomised to receive either Fluzone High-Dose or Fluzone (2006-2007 formulation). The study compared the safety and immunogenicity of Fluzone High-Dose to those of Fluzone. The safety analysis set included 2573 Fluzone High-Dose recipients and 1260 Fluzone recipients.

Table 6 summarizes solicited injection-site reactions and systemic adverse events reported within 7 days post-vaccination via diary cards. Onset was usually within the first 3 days after vaccination and a majority of the reactions resolved within 3 days. Solicited injection-site reactions and systemic adverse events were more frequent after vaccination with Fluzone High-Dose compared to Fluzone.

Table 6 - FIM05: Frequency of Solicited Injection-Site Reactions and Systemic Adverse Events Within 7 Days After Vaccination with Fluzone High-Dose or Fluzone, Adults 65 Years of Age and Older

	Fluzone High-Dose (N[a]=2569-2572) Percentage			Fluzone (N[a]=1258-1260) Percentage		
	Any	Moderate[b]	Severe[c]	Any	Moderate[b]	Severe[c]
Injection-Site Pain	35.6	3.7	0.3	24.3	1.7	0.2
Injection-Site Erythema	14.9	1.9	1.8	10.8	0.8	0.6
Injection-Site Swelling	8.9	1.6	1.5	5.8	1.3	0.6
Myalgia	21.4	4.2	1.6	18.3	3.2	0.2
Malaise	18.0	4.7	1.6	14.0	3.7	0.6
Headache	16.8	3.1	1.1	14.4	2.5	0.3
Fever[d] (≥ 37.5ºC)	3.6	1.1	0.0	2.3	0.2	0.1

[a] N is the number of vaccinated participants with available data for the events listed

[b] Moderate - Injection-site pain: sufficiently discomforting to interfere with normal behaviour or activities; Injection-site erythema and Injection-site swelling: ≥2.5 cm to <5 cm; Fever: >38ºC to ≤39ºC; Myalgia, Malaise, and Headache: interferes with daily activities

[c] Severe - Injection-site pain: incapacitating, unable to perform usual activities; Injection-site erythema and Injection-site swelling: ≥5 cm; Fever: >39ºC; Myalgia, Malaise, and Headache: prevents daily activities

[d] Fever - The percentage of temperature measurements that were taken by oral route or not recorded were 97.9% and 2.1%, respectively, for Fluzone High-Dose; and 98.6% and 1.4%, respectively, for Fluzone.

Within 6 months post-vaccination, 156 (6.1%) Fluzone High-Dose recipients and 93 (7.4%) Fluzone recipients experienced a serious adverse event (SAE). No deaths were reported within 28 days post-vaccination. A total of 23 deaths were reported during Days 29 – 180 post-vaccination: 16 (0.6%) among Fluzone High-Dose recipients and 7 (0.6%) among Fluzone recipients. The majority of these participants had a medical history of cardiac, hepatic, neoplastic, renal, and/or respiratory diseases. These data do not provide evidence for a causal relationship between deaths and vaccination with Fluzone High-Dose.

FIM12 was a multi-centre, double-blind efficacy trial conducted in the US and Canada over two influenza seasons. In this study, adults 65 years of age and older were randomised to receive either Fluzone High-Dose or Fluzone (2011-2012 and 2012-2013 formulations). The study compared the efficacy and safety of Fluzone High-Dose to those of Fluzone. The safety analysis set included 15,992 Fluzone High-Dose recipients and 15,991 Fluzone recipients.

Within the study surveillance period (approximately 6 to 8 months post-vaccination), 1323 (8.3%) Fluzone High-Dose recipients and 1442 (9.0%) Fluzone recipients experienced an SAE. Within 30 days post-vaccination, 204 (1.3%) Fluzone High-Dose recipients and 200 (1.3%) Fluzone

recipients experienced an SAE. The majority of these participants had one or more chronic comorbid illnesses. A total of 167 deaths were reported within 6 to 8 months post-vaccination: 83 (0.5%) among Fluzone High-Dose recipients and 84 (0.5%) among Fluzone recipients. A total of 6 deaths were reported within 30 days post-vaccination: 6 (0.04%) among Fluzone High-Dose recipients and 0 (0 %) among Fluzone recipients. These data do not provide evidence for a causal relationship between deaths and vaccination with Fluzone High-Dose.

Adverse Reactions from Post-Marketing Surveillance

The following events have been spontaneously reported during the post-approval use of Fluzone or Fluzone High-Dose. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure. Adverse events were included based on one or more of the following factors: severity, frequency of reporting, or strength of evidence for a causal relationship to Fluzone or Fluzone High-Dose.

- *Blood and Lymphatic System Disorders*: Thrombocytopaenia, lymphadenopathy
- *Immune System Disorders:* Anaphylaxis, other allergic/hypersensitivity reactions (including urticaria, angioedema)
- *Eye Disorders*: Ocular hyperaemia
- *Nervous System Disorders:* Guillain-Barré syndrome (GBS), convulsions, febrile convulsions, myelitis (including encephalomyelitis and transverse myelitis), facial palsy (Bell's palsy), optic neuritis/neuropathy, brachial neuritis, syncope (shortly after vaccination), dizziness, paraesthesia
- *Vascular Disorders:* Vasculitis, vasodilatation/flushing
- *Respiratory, Thoracic and Mediastinal Disorders:* Dyspnoea, pharyngitis, rhinitis, cough, wheezing, throat tightness
- *Skin and Subcutaneous Tissue Disorders:* Stevens-Johnson syndrome
- *General Disorders and Administration Site Conditions:* Pruritus, asthenia/fatigue, pain in extremities, chest pain
- *Gastrointestinal Disorders:* Vomiting, diarrhoea

DOSAGE AND ADMINISTRATION

Fluzone High-Dose should be given in accordance with the national recommendation as per the current Immunisation Handbook.

Fluzone High-Dose should be administered as a single 0.5 mL injection by the intramuscular route in adults 65 years of age and older.

Injections of Fluzone High-Dose should be administered intramuscularly, preferably in the deltoid muscle in the elderly. The vaccine should not be injected into the gluteal region, or into areas where there may be a major nerve trunk.

For needle size and length, refer to the national recommendations as per the current Immunisation Handbook.

Before administering a dose of vaccine, shake the prefilled syringe.

Inspect Fluzone High-Dose visually for particulate matter and/or discolouration prior to administration. If any of these defects or conditions exist, the vaccine should not be administered.

The syringe is for single use only and must not be reused. Discard any remaining unused contents.

Fluzone High-Dose should not be mixed with any other vaccine in the same syringe or vial.

OVERDOSE

For general advice on overdose management, contact the Poisons Information Centre, telephone number 13 11 26.

PRESENTATION AND STORAGE CONDITIONS

Fluzone High-Dose is available as a 0.5 mL single-dose, pre-filled syringe without needle. Packs of 5 or 10 syringes.

Store at 2°C to 8°C (Refrigerate, Do not freeze). Discard if vaccine has been frozen.

NAME AND ADDRESS OF THE SPONSOR

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POISON SCHEDULE OF THE MEDICINE

S4 Prescription Only Medicine

DATE OF FIRST INCLUSION IN THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS (ARTG)

21 December 2017

DATE OF MOST RECENT AMENDMENT

12 January 2018