Immunogenicity Against Heterologous Strains (variants from those included in the vaccine)

The antibody responses, as measured by Geometric Mean Ratios (GMRs), against all three heterologous influenza strains were higher for FLUAD Pediatric® than those for the comparator vaccines 3 weeks and six months after administration of the second vaccine dose (Day 50 and Day 209, respectively; Table 7 and Table 8).

Seroconversion (SC) rates against all three heterologous influenza strains were also higher for FLUAD Pediatric® than for the comparator vaccines 3 weeks after administration of the second vaccine dose (Day 50; Table 7).

Table 7 Immunogenicity (Heterologous Strains) of FLUAD Pediatric® in Children 6 months to <2 years of age at Day 50

	Day 50 (3 weeks after second dose)			
	FLUAD Pediatric® (aTIV) N = 132	**TIV 1 N = 216**	**TIV 2 N = 214**	**Ratios or Differences between vaccine groups**
H1N1				
GMR[a] (95% CI)	3.08 (2.54-3.75)	1.83 (1.57-2.14)	1.64 (1.41-1.92)	aTIV:TIV1 = **1.68** **(1.31-2.16)** aTIV:TIV2 = **1.88** **(1.46-2.41)**
% SC[b] (95% CI)	32 (24-40)	21 (16-27)	20 (15-26)	aTIV - TIV1 = **11** **(1.1-20.3)** aTIV - TIV2 = **12** **(2.8-21.9)**
H3N2				
GMR[a] (95% CI)	13 (10-15)	3.42 (2.93-4)	4.55 (3.9-5.32)	aTIV:TIV1 = **3.69** **(2.87-4.74)** aTIV:TIV2 = **2.78** **(2.16-3.57)**
% SC[b] (95% CI)	90 (84-95)	38 (32-45)	47 (40-54)	aTIV - TIV1 = **52** **(42.9-59.4)** aTIV - TIV2 = **43** **(34-50.9)**
B				
GMR[a] (95% CI)	22 (18-26)	4.64 (4.03-5.34)	5.34 (4.63-6.15)	aTIV:TIV1 = **4.71** **(3.75-5.93)** aTIV:TIV2 = **4.1 (3.26-5.16)**
% SC[b] (95% CI)	96 (91-99)	44 (38-51)	46 (39-53)	aTIV - TIV1 = **52** **(44.2-59)** aTIV - TIV2 = **50** **(42.1-57.1)**

[a] GMR = geometric mean ratio = Ratio of Day 50:Day 1 geometric mean titres; [b] SC = seroconversion or significant increase = the percentage of subjects achieving ≥4-fold increase in HI titre from a seropositive pre-vaccination titre (≥10), or, an HI titre ≥40 from a seronegative (<10) pre-vaccination titre. Vaccine group ratios adjusted for baseline titre. **Bold** indicates higher HI antibody response in favour of the Fluad Pediatric® group. TIV 1= Novartis licensed subunit vaccine, TIV 2= Sanofi licensed split vaccine.

Table 8 Immunogenicity (Heterologous Strains) of FLUAD Pediatric® in Children 6 months to <2 years of age at Day 209

	Day 209 (6 months after second dose)			
	FLUAD Pediatric® (aTIV) N = 132	**TIV 1 N = 216**	**TIV 2 N = 214**	**Ratios or Differences between vaccine groups**
H1N1				
GMR[a] (95% CI)	1.48 (1.31-1.67)	1.33 (1.21-1.46)	1.24 (1.13-1.37)	aTIV:TIV1 = 1.11 (0.95-1.3) aTIV:TIV2 = **1.19** **(1.02-1.39)**
% SC[b] (95% CI)	16 (10-23)	11 (7-16)	6 (3-10)	aTIV - TIV1 = 5 (-1.9-13.3) aTIV - TIV2 = **10** **(3.3-17.5)**
H3N2				
GMR[a] (95% CI)	2.36 (1.97-2.83)	1.45 (1.26-1.67)	1.67 (1.44-1.92)	aTIV:TIV1 = **1.63** **(1.29-2.05)** aTIV:TIV2 = **1.42** **(1.12-1.79)**
% SC[b] (95% CI)	24 (17-32)	13 (9-19)	16 (12-22)	aTIV - TIV1 = **11** **(2.5-19.8)** aTIV - TIV2 = 8 (-1-17.1)
B				
GMR[a] (95% CI)	3.64 (3.18-4.17)	1.47 (1.32-1.63)	1.59 (1.43-1.77)	aTIV:TIV1 = **2.48** **(2.09-2.95)** aTIV:TIV2 = **2.28 (1.92-2.71)**
% SC[b] (95% CI)	27 (19-35)	10 (6-15)	10 (6-15)	aTIV - TIV1 = **16** **(8.2-25.3)** aTIV - TIV2 = **17** **(8.5-25.6)**

[a] GMR = geometric mean ratio = Ratio of Day 50:Day 1 geometric mean titres; [b] SC = seroconversion or significant increase = the percentage of subjects achieving ≥4-fold increase in HI titre from a seropositive pre-vaccination titre (≥10), or, an HI titre ≥40 from a seronegative (<10) pre-vaccination titre. **Bold** indicates higher HI antibody response in favour of the Fluad Pediatric® group. TIV 1= Novartis licensed subunit vaccine, TIV 2= Sanofi licensed split vaccine.

Elderly Population

Evaluation of vaccine immunogenicity was originally based on the CHMP criteria defined in the CPMP/BWP/214/96 guideline. Generally all 3 CHMP criteria were met with FLUAD® for each strain (see Table 9 below). When not all 3 criteria were met, the GMR and seroconversion/significant increase CHMP criteria were more frequently achieved with FLUAD® than with the comparator vaccine. Table 9CHMP Criteria Fulfilled Against Homologous Influenza Strains After One Vaccination[a] - HI assay (PP-Population)

	V7P5		V7P8		V7P17		V7P24		V7P34	
	FLUAD® (w)	AGRIFLU*	FLUAD® (w)	AGRIFLU*	FLUAD® (w)	AGRIFLU*	FLUAD® (c)	Flushield	FLUAD® (c)	AGRIFLU*
	N=94	N=97	N=100	N=99	N=147	N=150	N=140	N=140	N=211	N=106
H3N2	3/3	3/3	3/3	2/3	3/3	3/3	3/3	3/3	1/3	1/3
H1N1	3/3	2/3	1/3	1/3	3/3	2/3	2/3	2/3	3/3	2/3
B	3/3	2/3	3/3	2/3	3/3	3/3	3/3	2/3	3/3	2/3

Source: FLUAD*(w) = 'water' formulation (FLUAD*/MF59W.1); FLUAD*(c) = 'citrate' formulation (FLUAD*/MF59C.1); Note: for all studies only results with FLUAD* (single syringe) are presented;
[a]i.e., on day 28.

In all five pivotal clinical trials consistent numerically higher HI antibody titers (i.e., day 28 GMT FLUAD®/comparator ratio >1) and greater percentages of subjects achieving seroconversion or significant increase in HI titres (i.e., vaccine group difference for the seroconversion rate of FLUAD®/comparator >0) for homologous strains were observed for FLUAD®. The differences were statistically significant for some strains and/or some endpoints (see Table 10 and Table 11). However, clinical relevance of the difference is unknown.

Table 10: Postvaccination GMTs and Vaccine Group Ratios - HI assay (PP-Population)

Study	Antigen	FLUAD®		Comparator		
		N	GMT (95% CI)	N	GMT (95% CI)	Vaccine Group Ratio (99.17% CI)#
V7P5	H3N2	94	331 (271-406)	97	161 (132-196)	2.06 (1.4-3.03) §
	H1N1	94	252 (214-297)	97	179 (152-211)	1.41 (1.03-1.92) §
	B	94	137 (115-162)	97	85 (71-100)	1.62 (1.17-2.24) §
V7P8	H3N2	100	121 (69-210)	99	62 (37-104)	1.94 (1.25-3.01) §
	H1N1	100	179 (121-265)	99	153 (106-220)	1.17 (0.86-1.6)
	B	100	77 (52-115)	99	60 (41-86)	1.3 (0.95-1.78)
V7P17	H3N2	147	276 (228-335)	150	153 (127-185)	1.81 (1.25-2.61) §
	H1N1	147	367 (314-429)	150	266 (228-311)	1.38 (1.03-1.85) §
	B	147	289 (250-335)	150	206 (178-238)	1.41 (1.07-1.86) §
V7P24	H3N2	140	251 (213-295)	140	204 (173-240)	1.23 (0.9-1.68)
	H1N1	140	223 (183-272)	140	217 (178-266)	1.03 (0.7-1.5)
	B	140	182 (149-222)	140	133 (109-162)	1.37 (0.94-2.0)
V7P34	H3N2	211	243 (220-267)	106	203 (177-233)	1.19 (0.95-1.5)
	H1N1	211	203 (175-235)	106	155 (126-190)	1.31 (0.93-1.85)
	B	211	168 (147-191)	106	140 (116-168)	1.2 (0.89-1.63)

2-sided 99.17% Bonferroni adjusted CI within each study for 6 comparisons (3 strains by 2 endpoints).
§indicate that if CI does not contain 1, i.e. statistically significant difference.

Table 11: Postvaccination SC and Vaccine Group Differences - HI assay (PP-Population)

Study	Antigen	FLUAD®		Comparator		
		N	SC (95% CI)	N	SC (95% CI)	Vaccine Group Difference (99.17% CI)#
V7P5	H3N2	94	83 (74-90)	97	61 (50-71)	22 (5-38) §
	H1N1	94	32 (23-42)	97	23 (15-32)	9 (-8-26)
	B	94	52 (42-63)	97	30 (21-40)	22 (4-40) §
V7P8	H3N2	100	54 (44-64)	99	28 (20-38)	26 (7-42) §
	H1N1	100	23 (15-32)	99	11 (6-19)	12 (-2-26)
	B	100	35 (26-45)	99	27 (19-37)	8 (-10-25)
V7P17	H3N2	147	55 (47-63)	150	36 (28-44)	19 (4-33) §
	H1N1	147	35 (27-43)	150	23 (17-31)	11 (-3-25)
	B	147	48 (40-57)	150	33 (25-41)	16 (1-30) §
V7P24	H3N2	140	56 (48-65)	140	35 (27-44)	21 (6-36) §
	H1N1	140	26 (19-35)	140	24 (17-32)	2 (-12-16)
	B	140	41 (32-49)	140	27 (20-35)	14 (-1-28)
V7P34	H3N2	211	23(18-30)	106	18(11-27)	5 (-8-17)
	H1N1	211	40 (33-47)	106	30 (22-40)	10 (-6-24)
	B	211	41 (34-48)	106	25 (17-34)	16 (1-30) §

SC = seroconversion or significant increase.
# 2-sided 99.17% Bonferroni adjusted CI within each study, for 6 comparisons (3 strains by 2 endpoints).
§ indicate that if CI does not contain 0, i.e. statistically significant difference.

Postvaccination GMTs and seroconversion rates for heterologous strains were observed to be consistently higher for FLUAD® than for AGRIFLU®. The difference was statistically significant for some strains and/or some endpoints (see Table 12).

Table 12 GMT and Seroconversion Response to Heterologous Influenza Strains After One Vaccination [a] – Study V7P3 - HI assay (PP-Population)

		FLUAD®	AGRIFLU*	Vaccine Group Comparisons (99.17% CI)#
		N=39	N=35	
H3N2	GMT (95% CI)	173 (117-256)	99 (65-150)	1.75 (0.81-3.8)
	% SC (95% CI)	79 (64-91)	46 (29-63)	34 (4-58) §
H1N1	GMT (95% CI)	270 (200-365)	133 (97-183)	2.03 (1.12-3.67) §
	% SC (95% CI)	74 (58-87)	37 (21-55)	37 (7-61) §
B	GMT (95% CI)	200 (153-261)	105 (79-139)	1.9 (1.12-3.24) §
	% SC (95% CI)	92 (79-98)	69 (51-83)	24 (0-48)

SC= seroconversion or significant increase, i.e., ≥4-fold increase in HI titer from a pre-vaccination titer ≥1:10 or a rise from <1:10 to ≥1:40 in those who were serum-negative at baseline;
[a] i.e., on day 28.
2-sided 99.17% Bonferroni adjusted CI within each study, for 6 comparisons (3 strains by 2 endpoints).
§ indicate statistically significant difference/ratio.

Seroprotection GMR and rates for heterologous strains were observed to be consistently higher for FLUAD® than for AGRIFLU* (see Table 13).

Table 13 Seroprotection and GMR Immune Response to Heterologous Influenza Strains After One Vaccination[a] – Study V7P3 - HI assay (PP-Population)

		FLUAD®	AGRIFLU*
		N=39	N=35
H3N2	% SP (95% CI)	100 (91-100)	83 (66-93)
	GMR (95% CI)	7.86 (5.41-11)	4.08 (2.75-6.06)
H1N1	% SP (95% CI)	100 (91-100)	94 (81-99)
	GMR (95% CI)	5.32 (3.84-7.36)	2.54 (1.8-3.57)
B	% SP (95% CI)	100 (91-100)	97 (85-100)
	GMR (95% CI)	9.06 (7.08-12)	3.84 (2.96-4.99)

SP= seroprotection, i.e., HI titer ≥1:40, GMR= day 28/day 0 geometric mean titer ratio.
[a] i.e., on day 28.

TOXICOLOGY

Nonclinical Toxicology Studies

Study type, gender, and species	**Route and regimen[a]**	**Results**
Repeat dose toxicity - male and female rabbits	Two or three 0.5 mL intramuscular doses of FLUAD® two weeks apart	There were no systemic adverse effects, and FLUAD® was well tolerated locally.
Delayed contact hypersensitivity - female Guinea pigs	Intradermal 0.1 mL and topical 0.5 mL doses of FLUAD® during induction phase, and topical 0.5 mL dose of FLUAD® during challenge phase.	FLUAD® was not a skin sensitiser in Guinea pigs in this study.

[a]On a body weight basis, each dose administered to rabbits was approximately 15 times the human dose

FLUAD® has not been evaluated for reproductive and developmental toxicity, carcinogenic or mutagenic potential.

REFERENCES

1 Advisory Committee on Immunization Practices (ACIP) 2013. Prevention and Control of Influenza with Vaccines. MMWR 2013; 62 (RR-07): 1-48.

2 Canada Communicable Disease Report (CCDR), November 15, 2001; V.27.

3 Colombo *et al.*, Rev. Epidemiol. Santé Publique 2001 April; 49 (2): 157-16.

4 Glathe H., Lange W. Influenza Vaccination in Older Patients *Drugs Aging* 1995; 6 (5): 368-387.

5 Gross P.A., Hermogenes A.W., Sacks H.S., *et.al*. The Efficacy of Influenza Vaccine in Elderly Persons - A Meta-analysis and Review of the Literature. *Ann Intern Med* .1995; 123 (7): 518-527.

6 FDA Guidance for Industry: Clinical Data Needed to Support the Licensure of Seasonal Inactivated Influenza Vaccines. CBER, May 2007.

7 Hamdy RC, Micklewright M, Beecham VF, Moore SW. Influenza vaccine may enhance theophylline toxicity. A case report and review of the literature. Journal of the Tennessee Medical Association 1995;88:463-4.

8 Monto S.A. Influenza: Quantifying Morbidity and Mortality. *Am J Med* Jun 1987; 82 (6A): 20-25.

9 National Advisory Committee on Immunization (NACI). Statement on seasonal trivalent inactivated influenza vaccine (TIV) for 2013-2014. CCDR 2013;39(ACS-4):1-37.

10 Spila-Alegiani *et al.*, Reactogenicity in the elderly of nine commercial influenza vaccines: results from the Italian SVEVA study, Vaccine 17 (1999) 1898-1904.

11 Souto JC, Oliver A, Montserrat I, Mateo J, Sureda A, Fontcuberta J. Influenza immunization is a safe procedure in patients undergoing long-term anticoagulation. Arch Intern Med 1996;156:1589-92.

PART III: CONSUMER INFORMATION

FLUAD Pediatric® and FLUAD®

(Influenza Virus Vaccine, surface antigen, inactivated,
Adjuvanted with MF59C.1)

This leaflet is part III of a three-part "Product Monograph" published when FLUAD Pediatric®/FLUAD®was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about FLUAD Pediatric®/FLUAD®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS VACCINE

What the vaccine is used for:

FLUAD Pediatric®/FLUAD® is an inactivated influenza virus vaccine against influenza subtypes A and B contained in the vaccine, indicated in children 6 months to less than 2 years of age and adults 65 years of age and older.

What it does:

FLUAD Pediatric®/FLUAD® provides active immunization of persons 6 months to less than 2 years of age and persons 65 years of age and older against influenza disease, used to prevent people from developing influenza (the flu), or reduce flu symptoms.

Like other influenza vaccines FLUAD Pediatric®/FLUAD® causes the body to produce antibodies against the virus. This means that when your body is exposed to the flu virus, your body is able to defend itself. The antibodies stop the attacking virus. You cannot catch influenza from the vaccine, since it only contains portions of the virus, and not the whole live virus. Your body takes 2 to 3 weeks to produce antibodies after vaccination. Therefore, if you are exposed to influenza immediately before or after your vaccination, you could still develop the illness. The vaccine will not protect you against the common cold, even though some of the symptoms are similar to influenza. Influenza viruses change all the time, so different vaccines are made every year. To stay protected against influenza, you need to be re-vaccinated every year before the winter season.

It is particularly important for some groups of people to be vaccinated. These include people with certain medical conditions, elderly people, people who are likely to be exposed to the infection and people on certain medications. If you are in doubt as to whether you should be vaccinated, talk to your local health professionals.

FLUAD Pediatric®/FLUAD® follows the World Health Organisation (WHO) and National Advisory Committee on Immunization (NACI) recommendation for vaccination for the northern hemisphere for the 2020-2021 season.

When it should not be used:

FLUAD Pediatric®/FLUAD® should not be used where there is a history of hypersensitivity to egg proteins or other components of the vaccine, any of the excipients or in people who have had a life-threatening reaction to previous influenza vaccination. (For a complete listing, see the Dosage Forms, Composition and Packaging section of the Product Monograph).

What the medicinal ingredients are:
Influenza virus vaccine (surface antigen, inactivated) subtypes A and B (/2020/2021 season).

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

A/Guangdong-Maonan/SWL1536/2019 (H1N1) pdm09-like virus,
A/Hong Kong/2671/2019 (H3N2)-like virus,
B/Washington/02/2019-like virus.
This vaccine complies with the WHO recommendations (northern hemisphere) for the 2020/2021 season.

What the important nonmedicinal ingredients are:

Sodium chloride, Potassium chloride, Potassium dihydrogen phosphate, Disodium phosphate dihydrate, Magnesium chloride hexahydrate, Calcium chloride dihydrate, Squalene, Polysorbate 80, Sorbitan trioleate, Sodium citrate, Citric acid and Water for Injections.

May also contain trace amounts of:

Neomycin, kanamycin, hydrocortisone, egg proteins, formaldehyde, or cetyltrimethylammonium bromide (CTAB), barium (residual).

For a full listing of nonmedicinal ingredients see Part 1 of the product monograph.

What dosage forms it comes in:

Each 0.5 mL dose contains 15 micrograms of influenza virus haemagglutinin (HA) and each 0.25 mL dose contains 7.5 micrograms of influenza virus HA from each of the following 3 strains:
A/Guangdong-Maonan/SWL1536/2019 (H1N1) pdm09-like virus,
A/Hong Kong/2671/2019 (H3N2)-like virus,
B/Washington/02/2019-like virus.

- Sterile suspension for intramuscular injection provided as one or ten single dose prefilled glass syringes (Type I), without needles.

- FLUAD Pediatric®/FLUAD® does not contain thimerosal or any other preservative.
- The syringe plunger does not contain latex and FLUAD® is considered safe for use in persons with latex allergies

WARNINGS AND PRECAUTIONS

FLUAD® should not be administered to anyone with known allergies to eggs or egg products, or any other constituent of the vaccine or to anyone who has had a life-threatening reaction to previous influenza vaccination.

If Guillain-Barré Syndrome (GBS) has occurred within six weeks of previous influenza vaccination, the decision to give FLUAD® should be based on careful consideration of the potential benefits and risks.

Immunocompromised patients may have a diminished immune response to FLUAD Pediatric®/FLUAD®.

BEFORE you or your child receives FLUAD Pediatric®/FLUAD®, talk to your doctor or pharmacist if:

- You or your child are/is allergic to eggs or egg-products
- You or your child are/is allergic to any of the following: kanamycin and neomycin sulphate, hydrocortisone, formaldehyde, cetyltrimethylammonium bromide, or polysorbate 80
- You or your child have/has a fever, or you think you may be getting a fever
- You or your child had a serious reaction to any flu vaccine in the past
- You or your child have/has any known allergies
- You or your child have/has experienced any health problems
- You are pregnant: ask your doctor for advice
- You or your child are/is currently on any medication (i.e. immunosuppressant, theophylline, anticoagulants such as warfarin)

FLUAD® may be given at the same time as other vaccines. There are no data to assess the concomitant administration of FLUAD Pediatric® with other vaccines.
Do not mix with any other vaccine in the same syringe.
As with any vaccine, immunization with FLUAD® may not protect 100% of individuals against influenza disease.

Immunosuppressive therapies may reduce immune response to FLUAD Pediatric®/FLUAD®.

USE IN SPECIFIC POPULATIONS

- Safety and effectiveness of FLUAD® has not been established in pregnant women and nursing mothers.
- Safety and effectiveness in children over 2 years of age and adolescents has not been established.
- Antibody responses were lower in the geriatric population than in younger adult subjects.

INTERACTIONS WITH THIS VACCINE

Overview

No interaction between FLUAD Pediatric®/FLUAD® and other vaccines or medication is known.

Drug-Drug Interactions

FLUAD® may be given at the same time as other vaccines. There are no data to assess the concomitant administration of FLUADPediatric® with other vaccines. FLUAD Pediatric®/FLUAD® should not be mixed with any other vaccine in the same syringe. Immunization should be carried out on separate limbs. It should be noted that the systemic adverse reactions may be intensified.

The immunological response may be diminished if the patient is undergoing immunosuppressant treatment.

Although a possible interaction has been suggested in the literature between influenza vaccination and the use of warfarin and theophylline, clinical studies have not shown any adverse effects attributable to these drugs in people receiving influenza vaccine. There were no studies designed to evaluate the drug interactions with FLUAD Pediatric®/FLUAD®.

PROPER USE OF THIS VACCINE

Usual dose:
Children 6 months to <2 years of age: A single dose of 0.25 mL.

Children 6 months to <2 years of age who have not been previously vaccinated against influenza, should receive a second dose after at least 4 weeks.

Adults aged 65 years and over: A single dose of 0.5 mL.

Immunization should be carried out by intramuscular injection only.

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.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control

Centre immediately, even if there are no symptoms.

No data are available.
Missed Dose: Not applicable

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Vaccination with FLUAD Pediatric®/FLUAD® (influenza vaccine, surface antigen, inactivated) cannot cause influenza because the vaccine does not contain live virus. Respiratory disease after vaccination represents coincidental illness unrelated to influenza vaccination.

Occasionally people have side effects with influenza vaccines. The most common of these are fever, feeling unwell, shivering, tiredness, headache, sweating, muscle joint pain, and warmth. Skin reactions include redness, swelling, pain, ecchymosis (blue/black staining of the skin) and a hardening of the skin at the injection site and itching. These reactions will normally disappear without treatment in a day or two.

Rarely, neuralgia (nerve pain), paresthesia (numbness and tingling), convulsions (seizures), thrombocytopenia (a blood disorder), lymphadenopathy (swelling of the glands in the neck, armpit or groin), muscular weakness, and allergic reactions (this might include but is not limited to breathing or swallowing difficulties, or swelling in the face or skin) have been reported with influenza vaccination. In rare cases, allergic reactions may lead to shock.

Very rarely, vasculitis (inflammation of blood vessels) temporarily affecting the kidneys, exudative erythema multiforme (severe skin rash), neurological disorders (affecting the nerves and brain), such as encephalomyelitis, and neuritis, injection-site cellulitis-like reaction (some cases of swelling, pain, and redness extending more than 10 cm and lasting more than 1 week) and extensive swelling of injected limb lasting more than one week have been reported.

The most common (≥10%) local adverse reactions observed in clinical studies for FLUAD® in the elderly population were injection site pain, induration, swelling, and erythema.

The most common (≥10%) systemic adverse reactions observed in clinical studies for FLUAD® in the elderly population were headache, myalgia, and malaise.

The most common (≥10%) local adverse reactions (after any vaccination) observed in clinical studies for FLUAD Pediatric® in children 6 months to <2 years of age were erythema, tenderness, and induration.

The most common (≥10%) systemic adverse reactions (after any vaccination) observed in clinical studies for FLUAD Pediatric® in children 6 months to <2 years of age were irritability, fever, vomiting , sleepiness, change in eating habits, diarrhea, and persistent crying.

This is not a complete list of side effects. For any unexpected effects while taking FLUAD Pediatric®/FLUAD®, *contact your doctor or pharmacist.*

HOW TO STORE IT

This product should be stored at 2°C to 8°C (in a refrigerator), not frozen. The syringe should be kept in the outer carton, thus protecting it from light.

FLUAD Pediatric®/FLUAD® can be administered following a 2 hour exposure at temperatures between 8° and 25°C. This is not, however, a recommendation for storage.

Do not use vaccine after the expiration date.

MORE INFORMATION

REPORTING SUSPECTED SIDE EFFECTS

To monitor vaccine safety, the Public Health Agency of Canada collects case reports on adverse events following immunization.

For health care professionals:
If a patient experiences an adverse event following immunization, please complete the appropriate Adverse Events following Immunization (AEFI) Form and send it to your local Health Unit in your province/territory.

For the General Public:
Should you experience an adverse event following immunization, please ask your doctor, nurse, or pharmacist to complete the Adverse Events following Immunization (AEFI) Form.

If you have any questions or have difficulties contacting your local health unit, please contact Vaccine Safety Section at Public Health Agency of Canada :

By toll-free telephone: 866-844-0018
By toll-free fax: 866-844-5931
Email: caefi@phac-aspc.gc.ca
Web: http://www.phac-aspc.gc.ca/im/vs-sv/index-eng.php

Mail:
The Public Health Agency of Canada
Vaccine Safety Section
130 Colonnade Road, A/L 6502A
Ottawa, ON K1A 0K9

NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying the Public Health Agency of Canada. The Public Health Agency of Canada does not provide medical advice

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This document plus the full product monograph, prepared for health professionals can be found at:

http://www.seqirus.ca
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Distributed by: Seqirus Canada Inc.
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Kirkland, Québec, H9H 4M7

Last revised: 2 April 2020