

PRODUCT INFORMATION LEAFLET

Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant)

**Pandemic Influenza Virus Vaccine
Monovalent, Inactivated Split Virion
Prepared in Eggs**

Suspension for Injection

ATC Code J07BB02

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Pandemic Influenza Virus Vaccine
Monovalent, Inactivated Split-Virion,
Prepared in Eggs

Version 2 approved July 22, 2010

Health Canada has authorized the sale of Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant) under the provision of an Interim Order (IO) issued on October 13, 2009. The authorization is based on the Health Canada review of the available data on quality, safety and immunogenicity, and given the pandemic threat at the time of authorization and its risk to human health, Health Canada considers that the benefit/risk profile of the of **Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant)** is favourable for active immunization against the 2009 pandemic H1N1 influenza strain.

This pandemic vaccine has been authorized based on data obtained with seasonal trivalent influenza vaccine, FLUVIRAL[®] and preliminary results with the pandemic unadjuvanted H1N1 vaccine manufactured by GSK in Dresden, Germany as well as preliminary safety data from studies with the Canadian manufactured vaccine.

This Product Information Leaflet is primarily based on the FLUVIRAL[®] Product Monograph and limited clinical data available for the pandemic unadjuvanted H1N1 vaccine at the time of authorisation.

More clinical data is being generated and the Product Information Leaflet will be updated based on additional data becoming available.

PLEASE CONSULT THE HEALTH CANADA WEBSITE FOR THE MOST UP-TO-DATE INFORMATION FOR THIS PRODUCT.

<http://www.hc-sc.gc.ca/dhp-mps/prodpharma/legislation/interimorders-arretesurgence/index-eng.php>

<http://www.hc-sc.gc.ca/dhp-mps/prodpharma/legislation/interimorders-arretesurgence/index-fra.php>

RECOMMENDATIONS MADE BY THE PUBLIC HEALTH AGENCY OF CANADA SHOULD ALSO BE TAKEN INTO CONSIDERATION.

<http://www.phac-aspc.gc.ca/alert-alerte/h1n1/vacc/recommendation-recommandation-eng.php>
<http://www.phac-aspc.gc.ca/alert-alerte/h1n1/fs-fi-pregnancy-grossesse-eng.php>

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1.0 PHARMACEUTICAL FORM

Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant) is a sterile suspension for intramuscular injection. It is a monovalent, inactivated, split-virion influenza vaccine prepared from virus grown in the allantoic cavity of embryonated hens' eggs. The virus is inactivated with ultraviolet light treatment followed by formaldehyde treatment, purified by centrifugation and disrupted with sodium deoxycholate.

Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant) is a translucent to whitish opalescent suspension that may sediment slightly.

2.0 QUALITATIVE AND QUANTITATIVE COMPOSITION

Table 1 Summary Product Information

Route of Administration	Dosage Form / Strength	Clinically Relevant Nonmedicinal Ingredients
IM	Suspension for Injection 15 µg influenza virus Hemagglutinin/ 0.5 mL dose	Thimerosal, trace amounts of egg proteins, formaldehyde, sodium deoxycholate and sucrose. <i>For a complete listing see 5.0 Pharmaceutical Particulars</i>

The composition of **Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant)** is:

15 µg HA - A/California/7/2009(H1N1)v-like strain (A/California/7/2009, NYMC X-179A (H1N1)v).

3.0 CLINICAL PARTICULARS

Indications

Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant) is indicated for the active immunization against the 2009 pandemic H1N1 influenza strain.

This indication is based on experience with the licensed FLUVIRAL[®] seasonal influenza vaccine, and limited clinical and nonclinical data available for the pandemic unadjuvanted H1N1 vaccine manufactured by GSK in Dresden, Germany as well as preliminary safety data from studies with the Canadian manufactured vaccine.

Dosage and Administration

There is currently limited clinical experience with Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant), and limited clinical experience with an investigational formulation of an unadjuvanted vaccine manufactured in Dresden, Germany, and Québec, Canada containing the same or a slightly higher amount of antigen derived from A/California/7/2009 (H1N1) (see section *Pharmacodynamics*) in healthy adults aged 18-60 years. There is no clinical experience yet in the elderly, adolescents or children.

The decision to use Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant) in each age group defined below should take into account the experience with FLUVIRAL®, the extent of the clinical data available with the unadjuvanted H1N1 vaccine, the disease characteristics of the current influenza pandemic and the recommendations of the Public Health Agency of Canada, which may change based on emerging additional data.

The dose recommendations are based on:

- the experience with the trivalent seasonal vaccine, FLUVIRAL®,
- limited immunogenicity data from 2 studies obtained three weeks after administration of a single dose of an investigational formulation of another unadjuvanted H1N1 vaccine manufactured in Dresden, Germany containing either 21 µg or 15 µg HA derived from A/California/7/2009 (H1N1) to healthy adults aged 18-60 years. See section *Pharmacodynamics*
- as well as preliminary safety data from studies with the Canadian manufactured vaccine.

Adults aged 18-60 years:

One dose of 0.5mL may be administered at an elected date.

The need for a second dose is currently unknown. However, preliminary immunogenicity data obtained at three weeks after administration of an investigational formulation of an unadjuvanted H1N1 vaccine containing either 21 µg or 15 µg HA (in a 0.5mL dose) derived from A/California/7/2009 (H1N1) to a limited number of healthy adults aged 18-60 years suggest that a single dose may be sufficient in this age group. See section *Pharmacodynamics*.

Elderly (>60 years):

No clinical data are available for Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant) in this age group. One dose of 0.5mL may be administered at an elected date.

Children and adolescents aged 10-17 years:

No clinical data are available for the Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant) in this age group. One dose of 0.5mL may be administered at an elected date.

Children aged 3-9 years:

No clinical data are available for the Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant) in this age group. The use of this vaccine should be considered in light of PHAC recommendations for the A/California/7/2009(H1N1)v-like vaccination. Preliminary data with other similar unadjuvanted vaccines suggest that if used in this age group, a 2-dose regimen (0.5mL with an interval of at least 21 days between doses) is recommended.

Children aged from 6-35 months:

No clinical data are available for the Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant) in this age group. The use of this vaccine should be considered in light of PHAC recommendations for the A/California/7/2009(H1N1)v-like vaccination. Preliminary data with other similar unadjuvanted vaccines suggest that for this age group, unadjuvanted vaccine may not be suitable against this pandemic strain.

Children aged less than 6 months:

Vaccination is not currently recommended in this age group.

For further information, see section *Pharmacodynamics*.

Method of administration:

Immunization should be carried out by intramuscular injection preferably into the deltoid muscle or anterolateral thigh (depending on muscle mass).

Contraindications

History of an anaphylactic reaction (i.e. life-threatening) to any of the constituents or trace residues of this vaccine.

See also section *Warnings and Precautions*.

Warnings and Precautions

Caution is needed when administering this vaccine to persons with a known hypersensitivity (other than anaphylactic reaction) to the active substance, to any of the excipients and to residues.

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.

If the pandemic situation allows, immunization shall be postponed in patients with severe febrile illness or acute infection.

Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant) should under no circumstances be administered intravascularly or intradermally.

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

A protective immune response may not be elicited in all vaccinees (see section *Pharmacodynamics*).

Pregnancy and Lactation

No data have been generated in pregnant or lactating women with Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant). Data from vaccinations with seasonal trivalent influenza vaccines in pregnant or lactating women do not indicate that adverse foetal and maternal outcomes were attributable to the vaccine.

CONSIDERATION SHOULD BE TAKEN OF THE RECOMMENDATIONS MADE BY THE PUBLIC HEALTH AGENCY OF CANADA.

Pediatrics:

No clinical data are available for the Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant) in children less than 10 years of age. For guidance on dosing in this age group, refer to the *Dosage and Administration* section.

CONSIDERATION SHOULD BE TAKEN OF THE RECOMMENDATIONS MADE BY THE PUBLIC HEALTH AGENCY OF CANADA.

Interactions

No data are available on the concomitant administration of **Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant)** with other vaccines, including seasonal trivalent influenza vaccines. Such data are in development, and this document will be amended to include them as soon as available. However, if co-administration with another vaccine is indicated, immunization 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.

Effects on Ability to Drive and Use Machines

No studies on the effects on the ability to drive and use machines have been performed.

Adverse Reactions

H1N1 (A/California/7/2009) Studies:

Preliminary reactogenicity (solicited local and general adverse events reported within 7 days of vaccination) are provided for 2 studies which evaluated the safety of another vaccine manufactured in Dresden, Germany containing HA derived from A/California/7/2009 (H1N1)v-like in healthy subjects aged 18-60 years. In one study, the unadjuvanted vaccine contained a higher amount of antigen (21 µg HA versus 15 µg). In both studies, a group of subjects received the vaccine without the AS03 adjuvant. Pain at the injection site was the most frequently reported solicited adverse events (AE). The frequency of “related” Grade 3 symptoms was 1.5%. Similar safety observations were recently made in another study (Q-Pan-H1N1-001) using the Canadian manufactured vaccine.

Table 2 D-Pan H1N1-021 (Day 0 to Day 6 solicited adverse events following a single dose of 21 µg HA unadjuvanted H1N1 vaccine) - Adverse Events with a causal relationship

Adverse reactions	H1N1 N=66
Pain	59.1%
Redness	4.5%
Swelling	1.5%
Fatigue	10.6%
Headache	7.6%
Arthralgia	3.0%
Myalgia	4.5%
Shivering	4.5%
Sweating	4.5%
Fever	0.0%

Table 3 D-Pan H1N1-007 (Day 0 to Day 6 solicited adverse events following a single dose of 15 µg HA unadjuvanted H1N1 vaccine) - Adverse Events with a causal relationship

Adverse reactions	H1N1 N=62
Pain	37.1%
Redness	0.0%
Swelling	0.0%
Fatigue	25.8%
Headache	7.6%
Arthralgia	4.8%
Myalgia	8.1%
Shivering	3.2%
Sweating	8.1%
Fever	0.0%

FLUVIRAL® Studies:

This section is based on the profile observed with FLUVIRAL® seasonal vaccine and are expected to be applicable to the **Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant)** as well.

Adverse Drug Reaction Overview

The most commonly reported adverse drug reactions with FLUVIRAL® are pain and redness at the injection site, fatigue, headache and myalgia. Common reactions are red eyes, sore throat, cough, arthralgia, swelling at the injection site, fever, chills, malaise and chest tightness. Reactions are generally mild and of limited duration. Prophylactic acetaminophen may decrease the frequency of some side effects in adults.

Immediate, allergic-type responses, such as hives, angioedema, allergic asthma, or systemic anaphylaxis occur extremely rarely. These reactions probably result from sensitivity to some vaccine component - most likely residual egg proteins (see **CONTRAINDICATIONS**).

FLUVIRAL® was administered to 2,220 adult and elderly subjects in six clinical trials. General symptoms were solicited by a diary aid used by the subjects for 3 days post-vaccination.

Adverse reactions considered possibly related to vaccination have been categorised by frequency as follows.

- Very common ($\geq 1/10$)
- Common ($\geq 1/100$ to $< 1/10$)
- Uncommon ($\geq 1/1,000$ to $< 1/100$)
- Rare ($\geq 1/10,000$ to $< 1/1,000$)
- Very rare ($< 1/10,000$)

Infections and infestations

Uncommon: upper respiratory tract infection

Nervous system disorders

Very common: headache; Uncommon: dizziness

Eye disorders

Common: red eyes*

Respiratory, thoracic and mediastinal disorders

Common: sore throat*, cough*

Gastrointestinal disorders

Uncommon: nausea

Skin and subcutaneous tissue disorders

Uncommon: swelling of the face*

Musculoskeletal and connective tissue disorders

Very common: myalgia; Common: arthralgia

General disorders and administration site conditions

Very common: pain and redness at the injection site, fatigue; Common: swelling at the injection site, fever, chills, malaise, chest tightness*

*These symptoms can be associated to the oculo-respiratory syndrome (ORS). ORS consists of the following signs and symptoms: bilateral red eyes and/or respiratory symptoms (cough, wheeze, chest tightness, difficulty breathing, difficulty swallowing, hoarseness or sore throat) and/or facial swelling. Although not explicitly identified as ORS during the clinical trials, these symptoms were solicited to detect possible cases of that syndrome.

A study was conducted in 130 children aged 3-12 years. The data in the table below show the percentage of reported symptoms to FLUVIRAL[®] split-virion vaccine versus a competitor subvirion vaccine. The most frequently reported local reaction was soreness at the injection site and usually resolved in 1-2 days. The most common systemic reactions were headache, loss of appetite and muscle aches. There were no significant differences between the two groups.

Table 4 Percentage of subjects reporting symptoms

Subjects aged 3-12 years	Fluviral (n=65)	Competitor (n=65)
Local reactions (%)		
Soreness	57	58
Redness	12	14
Swelling	15	22
Limitation of movement	12	14
Systemic reactions (%)		
Headache	15	17
Loss of appetite	12	8
Muscle aches	14	11
Chills	3	6
Nausea	3	3
Vomiting	1	0
Diarrhea	6	6
Redness/rash	3	3

Post-Market Adverse Drug Reactions

There have been reports of neurological illnesses, including facial paralysis, encephalitis, encephalopathy, demyelinating disease and labyrinthitis, associated with trivalent inactivated influenza vaccines. Any relationship, other than a temporal one, to the vaccines has not been established. In the 1976 swine influenza vaccine campaign, an apparent association between receipt of the vaccine and subsequent development of Guillain-Barré syndrome was found. Since that time, studies in multiple years with vaccines prepared from other virus strains have failed to show a clear association of influenza vaccines with an increased frequency of Guillain-Barré syndrome. Influenza vaccine is not known to predispose to Reye's syndrome.

Post Marketing Surveillance

From Post-marketing surveillance with seasonal trivalent vaccines (without AS03), the following additional adverse events have been reported:

Blood and lymphatic system disorders

Transient thrombocytopenia.

Immune system disorders

Allergic reactions, in rare cases leading to shock.

Nervous system disorders

Neuralgia, convulsions.

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

Vascular disorders

Vasculitis with transient renal involvement.

Skin and subcutaneous tissue disorders

Generalised skin reactions including urticaria

Overdose

Insufficient data are available.

4.0 PHARMACOLOGICAL PROPERTIES

Mechanism of Action

Based on the Fluviral mechanism of action, it is anticipated that **Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant)**, split-virion inactivated influenza vaccine, promotes an active immunization against influenza strain A H1N1 contained in the vaccine. After injection of the vaccine there is an increase in circulating antibody to the viral hemagglutinin and peripheral blood lymphocytes are primed to respond to in vitro stimulation by vaccine antigens. As with other inactivated influenza vaccines, immunization is based on the humoral component of the specific immunological defense system, namely immunoglobulin G (IgG) antibodies against viral hemagglutinin (HA) and neuraminidase antigens. The effectiveness of inactivated influenza vaccines correlates with the age and immunocompetence of the vaccine recipient and the degree of similarity between the virus strains used in the preparation of the vaccines and those prevailing in the population.

Pharmacodynamics

No pharmacodynamic studies and no pharmacokinetics studies have been conducted with FLUVIRAL[®], nor **Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant)** in accordance with its status as a vaccine.

H1N1 (A/California/7/2009) Studies:

Health Canada will regularly review any new information which may become available and this labelling may be updated if necessary. The following data is currently available with the H1N1 strain with a pandemic potential.

Immune response to an investigational formulation of another vaccine without adjuvant, manufactured in Dresden, Germany, containing 15 µg HA derived from A/California/7/2009 (H1N1) in adults aged 18-60 years

In a clinical study that evaluated the immunogenicity of another vaccine without adjuvant containing 15 µg HA derived from A/California/7/2009 (H1N1)v-like in healthy subjects aged 18-60 years the anti-HA antibody responses post-dose 1 were as follows:

Table 5 Immunogenicity post-dose 1 of another vaccine without adjuvant containing 15 µg HA, in healthy subjects aged 18-60 years

Anti-HA antibody	Immune response to A/California/7/2009 (H1N1)v-like
	21 days after 1st dose N=66
Seroprotection rate ¹	93.9%
Seroconversion rate ²	84.8%
Seroconversion factor ³	31.0

¹ seroprotection rate: proportion of subjects with haemagglutination inhibition (HI) titre $\geq 1:40$;

² seroconversion rate: proportion of subjects who were either seronegative at pre-vaccination and have a protective post-vaccination titre of $\geq 1:40$, or who were seropositive at pre-vaccination and have a 4-fold increase in titre;

³ seroconversion factor: ratio of the post-vaccination geometric mean titre (GMT) and the pre-vaccination GMT.

Immune response to an investigational formulation of another vaccine without adjuvant, manufactured in Dresden, Germany, containing 21 µg HA derived from A/California/7/2009 (H1N1) in adults aged 18-60 years

In a clinical study that evaluated the immunogenicity of another vaccine without adjuvant containing 21 µg HA derived from A/California/7/2009 (H1N1)v-like in healthy subjects aged 18-60 years the anti-HA antibody responses post-dose 1 were as follows:

Table 6 Immunogenicity post-dose 1 of another vaccine without adjuvant, containing 21 µg HA, in adults aged 18-60 years

Anti-HA antibody	Immune response to A/California/7/2009 (H1N1)v-like
	21 days after 1st dose N=66
Seroprotection rate ¹	97.0%
Seroconversion rate ²	95.5%
Seroconversion factor ³	41.4

¹ seroprotection rate: proportion of subjects with haemagglutination inhibition (HI) titre $\geq 1:40$;

² seroconversion rate: proportion of subjects who were either seronegative at pre-vaccination and have a protective post-vaccination titre of $\geq 1:40$, or who were seropositive at pre-vaccination and have a 4-fold increase in titre;

³ seroconversion factor: ratio of the post-vaccination geometric mean titre (GMT) and the pre-vaccination GMT.

Pharmacokinetics

Evaluation of pharmacokinetic properties is not required for vaccines.

Non-Clinical Data

Preliminary results concerning protection against A/California/7/2009-like H1N1 have been generated in a challenge study in ferrets. Groups of immunologically-naïve animals were immunised with one or two doses of AS03-adjuvanted formulations containing from 1.9 to 15 µg HA of antigen (A/California/7/09 strain) manufactured in Germany, two doses of 15µg HA (A/California/7/09 strain) in an unadjuvanted formulation, or phosphate buffered saline (PBS) as control. Following vaccination, the ferrets underwent intratracheal challenge with a high dose of the closely related H1N1v virus A/The Netherlands/602/09.

Initial results indicate that a single vaccination with the AS03-adjuvanted formulations provide better protection than two injections of unadjuvanted antigen or PBS control against macroscopic lung pathology, and resulted in a significant reduction in virus titers in lung tissue. The proportion of lung tissue involved in pathology, and total lung weights, were lowest in animals that received adjuvanted vaccine. These results must be interpreted with caution, given that the animals were immunologically naïve with regard to all H1N1 influenza strains and the route of virus challenge may not represent typical human exposure.

5.0 PHARMACEUTICAL PARTICULARS

The composition of **Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant)** is:

15 µg HA - A/California/7/2009(H1N1)v-like strain (A/California/7/2009, NYMC X-179A (H1N1)v).

List of Excipients

The vaccine is formulated with phosphate buffered saline composed of: sodium chloride, potassium chloride, sodium phosphate dibasic heptahydrate, potassium phosphate monobasic and water for injection. Thimerosal 50 µg per 0.5 mL dose is added as a preservative. The vaccine also contains trace residual amounts of egg proteins, formaldehyde, sodium deoxycholate and sucrose. Antibiotics are not used in the manufacture of this vaccine.

Incompatibilities

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

Shelf Life

Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant) is stable for 18 months.

Do not use vaccine after the expiration date.

Special Precautions for Storage

Store at 2°C to 8°C (in a refrigerator).

Do not freeze. Freezing destroys activity. Do not use vaccine that has been frozen.

Store in the original packaging in order to protect from light.

Once entered, the multidose vial should be discarded after 28 days.

Nature and Contents of Container

Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant) is supplied in 10 mL vials holding 10 x 0.5 mL doses.

Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant) packaging does not contain latex.

Instructions for Use/Handling

Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant) is a translucent to whitish opalescent suspension that may sediment slightly. Inspect **Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant)** visually for discoloration prior to administration. If this condition exists, the vaccine should not be administered.

Shake the multidose vial vigorously each time before withdrawing a dose of vaccine.

Proper aseptic technique should be used for withdrawal of each dose from the multidose vial. Once entered, return the multidose vial to the recommended storage conditions, between 2°C and 8°C. Once entered, the multidose vial should be discarded after 28 days.

A separate sterile 1-cc syringe and needle or a sterile disposable 1-cc unit should be used for each injection to prevent transmission of hepatitis B, HIV, or other infectious agents from one person to another.

Disinfect the skin at the site of injection with a suitable antiseptic and wipe dry with sterile cotton wool. The injection of **Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant)** should be given intramuscularly, usually into the deltoid muscle. **Do not inject influenza vaccine intravenously.** No data are available on subcutaneous administration of **Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant)**, nor FLUVIRAL[®].

All vaccines should be observed for about 15 minutes after vaccination. If an anaphylactic reaction develops, sterile epinephrine hydrochloride (1:1000) should be administered.

Any unused product or waste material should be disposed of in accordance with local requirements. Since **Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant)** is an inactivated vaccine, it presents no risk of contaminating the work area during manipulation.

CONSUMER INFORMATION

Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant) Pandemic Influenza Virus Vaccine

This leaflet is part of a Product Information Leaflet and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about **Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant)**. Contact your doctor or pharmacist if you have any questions about the vaccine.

Health Canada has authorized the sale of **Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant)** under the provision of an Interim Order (IO) issued on October 13, 2009. The information provided is primarily based on the FLUVIRAL® Product Monograph and preliminary results with the pandemic unadjuvanted H1N1 vaccine manufactured by GSK in Dresden, Germany as well as preliminary safety data from studies with the Canadian manufactured vaccine.

Only limited clinical data were available for the pandemic unadjuvanted H1N1 vaccine at the time of authorisation.

More clinical data is being generated and the Product Information Leaflet will be updated based on additional data becoming available. Please consult the Health Canada website for the most up-to-date information for this product.

<http://www.hc-sc.gc.ca/dhp-mps/prodpharma/legislation/interimorders-arretesurgence/index-eng.php>
<http://www.hc-sc.gc.ca/dhp-mps/prodpharma/legislation/interimorders-arretesurgence/index-fra.php>

RECOMMENDATIONS MADE BY THE PUBLIC HEALTH AGENCY OF CANADA SHOULD ALSO BE TAKEN INTO CONSIDERATION.

<http://www.phac-aspc.gc.ca/alert-alerte/h1n1/vacc/recommandation-recommandation-eng.php>
<http://www.phac-aspc.gc.ca/alert-alerte/h1n1/fs-fi-pregnancy-grossesse-eng.php#s4>

Please read this leaflet carefully before receiving **Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant)** as it contains information about the vaccine. It may be useful to keep this leaflet in case you need to read it again after vaccination.

ABOUT THIS VACCINE

What the vaccine is used for:

Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant) is indicated for the active immunization against the 2009 pandemic H1N1 influenza strain.

Vaccination is the principal means of influenza prevention and associated complications.

What is Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant) and what does it do?

Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant) is a vaccine against influenza. It is an inactivated (killed) influenza (flu) virus vaccine in suspension for injection, which has been prepared in hens' eggs. The vaccine is made from the strain of flu virus which is causing the H1N1 flu 2009 pandemic.

Flu immunization does not prevent other virus infections that can cause coughs and colds. It protects only against the influenza virus that is contained in the vaccine and will take approximately 10 days following immunization to become effective.

What Is In Your Vaccine ?

- Each 0.5 mL dose of the vaccine contains 15 micrograms of highly purified sub-units (hemagglutinin) of strain A/California/7/2009, NYMC X-179A (H1N1)v. This is the flu virus that is causing the H1N1 flu 2009 pandemic. There is no live virus in this vaccine.
- **Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant)** contains thimerosal as a preservative. The vaccine also contains very small amounts of egg proteins, formaldehyde, sodium deoxycholate and sucrose.

What Dosage Forms Does Your Vaccine Come In?

Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant) is supplied in 10 mL vials holding 10x0.5mL doses. **Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant)** packaging does not contain latex.

WARNINGS AND PRECAUTIONS

Who should not receive the vaccine?

- People who have had a life-threatening allergic reaction to the vaccine or any of its components (e.g. egg, thimerosal)
- People with moderate to severe illness may have to delay immunization
- People who take oral theophylline or oral anticoagulants should consult with their physician before immunization
- Children under the age of 6 months

Make sure your prescriber knows if you have any of the following:

- any kind of infection or a high temperature at the moment
- a weakened immune system due to illness

- you are taking medicines which weaken the immune system (e.g. steroids such as prednisone)

INTERACTIONS WITH THIS VACCINE

Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant) may be given at the same time as other vaccines in a different arm.

PROPER USE OF THIS VACCINE

Adults and children/adolescents 10-17 years: one dose of 0.5 mL may be administered at an elected date.

Children 6-35 months:

No clinical data are available for the Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant) in this age group. The use of this vaccine should be considered in light of PHAC recommendations for the A/California/7/2009(H1N1)v-like vaccination. Preliminary data with other similar unadjuvanted vaccines suggest that for this age group, unadjuvanted vaccine may not be suitable against this pandemic strain.

Children (3-9 years)

No clinical data are available for the Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant) in this age group. The use of this vaccine should be considered in light of PHAC recommendations for the A/California/7/2009(H1N1)v-like vaccination. Preliminary data with other similar unadjuvanted vaccines suggest that if used for this age group, a 2-dose regimen (0.5mL with an interval of at least 21 days between doses) is recommended.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

As with all medicines, **Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant)** may cause side effects in some persons. If any side effects worry you, or you have any unusual symptoms, please contact your doctor, nurse or pharmacist.

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in cases of very rare but serious allergic reactions. This would normally happen immediately after the injection had been given - please tell the nurse if you get a rash, have tightness in the throat or shortness of breath.

If you notice any other side effects not mentioned below, please inform your doctor, nurse or pharmacist.

You may notice some pain, reddening or swelling at the site of the injection. In some cases you may feel unwell and experience fever or swelling of the lymph glands. More rarely headache,

shivering, sweating, tiredness and aches in your muscles and joints may occur. In addition, red eyes, respiratory problems and facial swelling may occur. These reactions are usually mild and should only last a day or two.

You should tell your doctor if you get any of the following unwanted effects: nerve pain (neuralgia), numbness / pins and needles (possibly with fever), convulsions, unexplained or easy bruising, skin rash, urinary symptoms

HOW TO STORE IT

Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant) should be stored in the refrigerator at +2° C to +8° C (DO NOT FREEZE). Do not use vaccine that has been frozen. Do not use vaccine after the expiration date.

REPORTING SUSPECTED SIDE EFFECTS

To monitor vaccine safety, the Public Health Agency of Canada collects information on serious and unexpected adverse events following vaccination. If you suspect you have had a serious or unexpected event following receipt of a vaccine you may notify the Public Health Agency of Canada:

By toll-free telephone: (613) 954-5590; 1-866-844-0018

By toll-free fax: (613) 954-9874; 1-866-844-5931

By email: caefi@phac-aspc.gc.ca;

By regular mail:

Vaccine Safety Section

Centre for Immunization & Respiratory Infectious Diseases,

Public Health Agency of Canada

130 Colonnade Road

Address Locator: 6502A

Ottawa, Ontario 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.

MORE INFORMATION

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

<http://www.gsk.ca> or by contacting the sponsor:

GlaxoSmithKline Inc.
7333 Mississauga Road
Mississauga, Ontario L5N 6L4
1-800-387-7374

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