CONSUMER INFORMATION

AGRIFLU®

(Influenza Virus Vaccine, surface antigen, inactivated)

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

ABOUT THIS MEDICATION

What the medication is used for:

AGRIFLU® is an inactivated influenza virus vaccine indicated for active immunization of persons 6 months of age and older against influenza disease caused by influenza virus subtypes A and B contained in the vaccine.

What it does:

AGRIFLU® provides active immunization of persons 6 months of age and older against influenza disease, used to prevent people from developing influenza (the flu), or reduce flu symptoms.

Like other influenza vaccines AGRIFLU® 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.

AGRIFLU® follows the World Health Organisation (WHO) and National Advisory Committee on Immunization (NACI) recommendation for vaccination for the northern hemisphere for the 2015/2016 season.

When it should not be used:

AGRIFLU® 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 (2015/2016 season)

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

A/California/7/2009 (H1N1)pdm09-like virus

A/California/7/2009 NYMC X-181 (H1N1); 15 micrograms HA

A/Switzerland/9715293/2013 (H3N2)-like virus

A/Switzerland/9715293/2013 NIB-88 (H3N2); 15 micrograms HA

B/Phuket/3073/2013-like virus (B/Brisbane/9/2014);

15 micrograms HA

Per 0.5 ml dose

§ haemagglutinin

This vaccine complies with the WHO recommendations (northern hemisphere) for the 2015/2016 season.

What the important nonmedicinal ingredients are:

Sodium chloride, Potassium chloride, Potassium dihydrogen phosphate, Disodium phosphate dihydrate, Magnesium chloride hexahydrate, Calcium chloride dihydrate, Water for Injection, Thimerosal (multi-dose vial only).

May also contain trace amounts of:

Neomycin, kanamycin, egg proteins, ovalbumin (residual), Formaldehyde, polysorbate 80, cetyltrimethylammonium bromide (CTAB), barium (residual), or citrates (residual).

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

What dosage forms it comes in:

Pre-filled Syringe:

Sterile suspension for intramuscular injection in pre-filled syringe provided as packages containing one or ten single dose pre-filled glass syringes (Type I), without needles. The syringe may be
fitted alternatively with a Luer Lock system.

AGRIFLU® pre-filled syringes do not contain thimerosal or any other preservative.

*Multi-dose vial:*
Provided as packages containing one or ten multi-dose Type I glass vials closed with a Type I, grey, siliconized, bromobutyl stopper.

AGRIFLU® multi-dose vials contain thimerosal as a preservative.

The syringe plunger and vial stopper do not contain latex and AGRIFLU® is considered safe for use in persons with latex allergies.

**WARNINGS AND PRECAUTIONS**

AGRIFLU® 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.

Immunization with AGRIFLU® shall be postponed in patients with febrile illness or acute infections.

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

Immunocompromised patients may have a diminished immune response to AGRIFLU®. It is possible that antibody response in patients with endogenous or iatrogenic immunosuppression may be insufficient.

**BEFORE you use AGRIFLU®, talk to your doctor or pharmacist if:**

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

AGRIFLU® may be given at the same time as other vaccines. Do not mix with any other vaccine in the same syringe.

As with any vaccine, immunization with AGRIFLU® may not protect 100% of individuals against influenza disease.

**INTERACTIONS WITH THIS MEDICATION**

**Overview**

No interaction between AGRIFLU® and other vaccines or medication is known.

**Drug-Drug Interactions**

AGRIFLU® may be given at the same time as other vaccines. AGRIFLU® should not be mixed with any other vaccine in the same syringe. Immunisation 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.

**PROPER USE OF THIS MEDICATION**

**Usual dose:**

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Dose</th>
<th>No. of Doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 to 35 months</td>
<td>0.25 mL or 0.5 mL</td>
<td>1 or 2</td>
</tr>
<tr>
<td>3 to 8 years</td>
<td>0.5 mL</td>
<td>1 or 2</td>
</tr>
<tr>
<td>&gt;9 years</td>
<td>0.5 mL</td>
<td>1</td>
</tr>
</tbody>
</table>

If half a dose (0.25 mL) is to be administered, discard half the contained volume (up to the mark indicated on the syringe barrel), before injection.

NACI recommends that children 6 to 35 months of age should be given a full dose (0.5 mL) of trivalent inactivated influenza vaccine (TIV) instead of the previously recommended half dose (0.25 mL). This NACI recommendation applies whether the child is being given one dose of TIV or a two dose series.

Immunization should be carried out by intramuscular injection.
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.**

Missed Dose: If a child’s second dose is missed, it can be given at any time.

### SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Vaccination with AGRIFLU® (influenza vaccine, surface antigen, inactivated) cannot cause influenza because the vaccine does not contain live virus.

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) 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, neurological disorders (affecting the nerves and brain), such as encephalomyelitis, and neuritis, injection-site cellulitis-like reactions (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 (injection-site) adverse reactions observed in clinical studies were injection site pain, induration, and erythema.

The most common (≥ 10%) systemic adverse reactions observed in clinical studies were headache, myalgia, and malaise.

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

### HOW TO STORE IT

AGRIFLU® should be stored at 2°C to 8°C (in a refrigerator), not frozen. The syringe and vial should be kept in the outer carton, thus protecting it from light. The multi-dose vial must be used within 28 days from the initial removal of the first dose (first needle puncture into vial) and between uses, return the multi-dose vial to the recommended storage conditions. The number of needle punctures should not exceed 10 per multi-dose vial.

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

The product has a shelf life of 1 year.

Do not use 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

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.
This leaflet was prepared by Novartis Vaccines and Diagnostics, S.r.l., Siena, Italy, an affiliate of: Novartis Vaccines and Diagnostics, Inc., 350 Massachusetts Avenue, Cambridge, MA USA 02139.

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

http://www.novartis.ca

or by contacting the distributor, Novartis Pharmaceuticals Canada Inc. at 1-800-363-8883

Distributed by:  Novartis Pharmaceuticals Canada Inc.
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Dorval, QC H9S 1A9

Last revised: June 19 2015