PART III: CONSUMER INFORMATION

[D]INFLUVAC®

influenza vaccine, surface antigen, inactivated

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

ABOUT THIS MEDICATION

What the medication is used for:

INFLUVAC is a vaccine used to prevent people from developing influenza (the flu), or reduce flu symptoms.

What it does:
Like other influenza vaccines, INFLUVAC 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 INFLUVAC since it only contains portions of the virus, and not the whole live virus. Your body takes 10 to 21 days 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 may be 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 care professionals.

INFLUVAC complies with the World Health Organization (WHO) and National Advisory Committee on Immunization (NACI) recommendations for vaccination in the northern hemisphere for the 2018/2019 season.

When it should not be used:
INFLUVAC vaccine is made in eggs; therefore this vaccine should not be given to anyone with allergies and especially severe allergies (anaphylactic reactions) to chicken eggs or egg products.

INFLUVAC should not be given to people who have allergies to the active substances, to any of the excipients and to residues of eggs, chicken protein, formaldehyde, cetyltrimethylammonium bromide, polysorbate 80, or gentamicin. For a complete listing of excipients, see the **DOSAGE FORMS, COMPOSITION AND PACKAGING** section of the Product Monograph.

Anyone who has experienced allergic reactions to a previous dose of influenza vaccine SHOULD NOT be vaccinated with INFLUVAC.

What the medicinal ingredient is:
The medicinal ingredient is surface antigens neuraminidase and haemagglutinin of the following viruses as recommended by WHO and the NACI: an A/Michigan/45/2015 (H1N1)pdm09-like virus, an A/Singapore/INFIMH-16-0019/2016 (H3N2)-like virus, and a B/Colorado/06/2017-like virus (B/Victoria/2/87 lineage).

What the other ingredients are:
Potassium chloride, potassium dihydrogen phosphate, disodium phosphate dihydrate, sodium chloride, calcium chloride dihydrate, magnesium chloride hexahydrate, and water for injection.

For a full listing of other (non-medicinal) ingredients, see the **DOSAGE FORMS, COMPOSITION AND PACKAGING** section of the Product Monograph.

What dosage forms it comes in:
INFLUVAC comes in a 0.5 mL pre-filled syringe for injection, List no. 0W184, containing neuraminidase and 15 mcg haemagglutinin of each of the following virus strains:

- A/Michigan/45/2015 (H1N1)pdm09-like strain (A/Singapore/GP1908/2015, IVR-180);
- A/Singapore/INFIMH-16-0019/2016 (H3N2)-like strain (A/Singapore/INFIMH-16-0019/2016, NIB-104);
- B/Colorado/06/2017-like strain (B/Victoria/2/87 lineage) (B/Maryland/15/2016, NYMC BX-69A).

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

INFLUVAC should not be used in individuals who are allergic to eggs, previous doses of the flu vaccine, or any components of the flu vaccine.

BEFORE you use INFLUVAC talk to your doctor or pharmacist if:

- you are allergic to eggs or egg-products
- you are allergic to any of the following: formaldehyde, cetyltrimethylammonium bromide, polysorbate 80 or gentamicin
- 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
- you are currently on any medication (i.e., immunosuppressants, theophylline, anticoagulants such as warfarin).

Fainting, feeling faint or other stress related reactions can occur following, or even before, any needle injection. Therefore tell your doctor or nurse if you have

experienced this kind of reaction with a previous injection.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with INFLUVAC include: immunosuppressants, theophylline, anticoagulants such as warfarin.

PROPER USE OF THIS MEDICATION

Usual Dose:
One dose of 0.5 mL pre-filled syringe containing neuraminidase and 15 mcg haemagglutinin per viral strain as recommended by WHO and NACI.

Adults and children from 3 years of age: 0.5 mL, single dose. For children, who have not previously been vaccinated, a second dose should be given after an interval of at least 4 weeks.

INFLUVAC comes as a 0.5 mL suspension, ready for intramuscular or deep subcutaneous injection. Allow the vaccine to reach room temperature (15-25°C) before use. Ensure that the product is returned to the refrigerator within 24 hours if not used.

Shake well before use.

Overdose:
Overdosage is unlikely to have any bad effect.

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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Occasionally people have side effects with influenza vaccines. The most common of these are fever, feeling unwell, shivering, tiredness, headache, sweating, muscle or joint pain, and warmth. Skin reactions include redness, swelling, pain, ecchymosis (blue/black staining of the skin), 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) and temporary thrombocytopenia (a blood disorder) have been reported. 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, neuritis and Guillain Barré syndrome have been reported.

Allergic reactions (this might include but is not limited to breathing or swallowing difficulties, or swelling in the face or skin), and temporary enlargement of the lymph nodes have been reported.

If you think that you have a side effect not mentioned here, please tell your doctor or pharmacist.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	fever	X		
	feeling unwell	X		
	shivering	X		
	tiredness	X		
	headache	X		
	sweating	X		
	muscle or joint pain	X		
	Skin Reactions			
	redness	X		
	swelling	X		
	pain	X		
	ecchymosis (blue/black staining of the skin)	X		
	reddening of the skin at the injection site	X		
Uncommon	nerve pain		X	
	numbness and tingling		X	
	convulsions (seizures)		X	
	temporary thrombocytopenia (a blood disorder)		X	
	allergic reactions		X	
	inflammation of blood vessels temporarily affecting the kidneys		X	
	brain disorders		X	
	Guillain Barré syndrome		X	

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

HOW TO STORE IT

INFLUVAC should only be given by a health care professional

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

Do not freeze. Store in the original package in order to protect from light.

Do not use after the expiry date.

This vaccine is effective against this year's 2018/2019 influenza virus.

REPORTING SUSPECTED SIDE EFFECTS

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

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 the Vaccine Safety Section at the Public Health Agency of Canada.

By toll-free telephone: 866-844-0018
By toll-free fax: 866-844-5931
E-mail: 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.

MORE INFORMATION

The most recent version of this document plus the full Product Monograph, prepared for health care professionals, can be found at: www.hc-sc.gc.ca (Drug Product Database) or at www.mylan.ca or by contacting the sponsor, BGP Pharma ULC, Etobicoke, Ontario, M8Z 2S6 at: 1- 844-596-9526

This leaflet was prepared by BGP Pharma ULC

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