

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 MEDICATIONWhat 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 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.

INFLUVAC follows the World Health Organisation (WHO) and National Advisory Committee on Immunization (NACI) recommendation for vaccination for the northern hemisphere for the 2010/2011 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 with 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 haemagglutinin and neuraminidase of the following viruses as recommended by WHO and the NACI:

an A/California/7/2009 (H₁N₁)-like virus, an A/Perth/16/2009 (H₃N₂)-like virus, a B/Brisbane/60/2008-like virus.

What the other ingredients are:

Potassium chloride, potassium dihydrogen phosphate, disodium phosphate dihydrate, sodium chloride calcium chloride dihydrate, magnesium chloride hexahydrate, water for injection.

For a full listing of other (nonmedicinal) 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 containing neuraminidase and 15 µg haemagglutinin of each of the following virus strains:

- A/California/7/2009 (H₁N₁)-like virus
- A/Perth/16/2009 (H₃N₂)-like virus
- B/Brisbane/60/2008-like virus

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: ask your doctor for advice
- You are currently on any medication (i.e. immunosuppressants, theophylline, anticoagulants such as warfarin)

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with INFLUVAC include: immunosuppressant, 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 µg haemagglutinin per viral strain as recommended by WHO and NACI.

Adults: 0.5 mL, single dose.

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.

Missed Dose:

Not applicable

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 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), 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 a 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 joint pain	X			
	<u>Skin reactions</u>				
	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 tingling		X		
	convulsions (seizures)		X		
	temporary thrombocytopenia (a blood disorder)		X		
	allergic reactions		X		
	inflammation of blood vessels		X		
	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°C to 8°C (in a refrigerator).

Protect from light and do not freeze.

Do not use after the expiry date.

This vaccine is effective against this year's 2010/2011 influenza virus.

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

By regular mail:
The Public Health Agency of Canada
Vaccine Safety Section
130 Colonnade Road
Ottawa, Ontario
K1A 0K9
A/L 6502A

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 monograph, prepared for health professionals can be found at:
<http://www.hc-sc.gc.ca> (Drug Product Database) or by contacting the sponsor, Abbott Laboratories Limited, at: 1-800-268-4276

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