PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

INFLUVAC®
influenza vaccine, surface antigen, inactivated

Suspension for Injection

Each 0.5 mL pre-filled syringe contains neuraminidase and 15 mcg haemagglutinin of each virus strain as recommended by the World Health Organization (WHO)

Active Immunizing Agent for the Prevention of Influenza
ATC Code: J07BB02

BGP Pharma.ULC
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Date of Initial Authorization: July 15, 2005

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RECENT MAJOR LABEL CHANGES

1 INDICATIONS, 1.1 Pediatrics	01/2025
4 DOSAGE AND ADMINISTRATION, 4.2 Recommended Dose and Dosage Adjustment; 4.4 Administration.	01/2025
7 WARNINGS AND PRECAUTIONS; 7.1.3 Pediatrics.	01/2025

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Sections or subsections that are not applicable at the time of authorization are not listed.

PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

INFLUVAC (influenza vaccine, surface antigen, inactivated) is indicated for:

- the prevention of influenza infection caused by the specific strains contained in the vaccine, in adults and children from 6 months of age and older.

1.1 Pediatrics

Pediatrics (< 6 months of age): The safety and efficacy of INFLUVAC in infants less than 6 months of age have not been established (See **14 CLINICAL TRIALS**).

1.2 Geriatrics

Geriatrics (> 65 years of age): INFLUVAC is indicated in people 65 years of age and over (see 1 **INDICATIONS**).

2 CONTRAINDICATIONS

The influenza virus for INFLUVAC (influenza vaccine, surface antigen, inactivated) is propagated in chicken eggs; therefore, this vaccine should not be administered to anyone with a history of hypersensitivity (allergy) and especially anaphylactic reactions to eggs or egg products. See 7 **WARNINGS AND PRECAUTIONS**.

Allergic reactions are extremely rare and are usually attributable to extreme sensitivity to certain components of the vaccine, probably to trace amounts of residual egg protein.

INFLUVAC should not be given to people who have a hypersensitivity to the active substances, to any of the excipients or to any component that may be present as traces such as eggs, chicken protein (such as ovalbumin), formaldehyde, cetyltrimethylammonium bromide, polysorbate 80, or gentamicin. For a complete listing, see 6 **DOSAGE FORMS, STRENGTH, COMPOSITION AND PACKAGING**.

Allergic or anaphylactic reactions to a previous dose of influenza vaccine are contraindications for vaccination.

Immunization with INFLUVAC should be deferred in the presence of any acute illness, including acute or unstable neurologic illness, febrile illness, or active infection.

A minor febrile illness such as mild upper respiratory infection is not usually reason to defer immunization.

4 DOSAGE AND ADMINISTRATION

4.2 Recommended Dose and Dosage Adjustment

- The recommended dose of INFLUVAC for adults above 18 years of age is 0.5 mL.
- The recommended dose of INFLUVAC for children from 6 months of age and older is 0.5 mL. For children less than 9 years of age, who have not previously been vaccinated, a second dose of 0.5 mL should be given after an interval of at least 4 weeks.

4.3 Reconstitution:

Parenteral Products:

- INFLUVAC comes as a 0.5 mL suspension ready for injection.

4.4 Administration

INFLUVAC should be administered by intramuscular or deep subcutaneous injection.

The preferred sites for intramuscular injection are the anterolateral aspect of the thigh (or the deltoid muscle if muscle mass is adequate) in children 6 months through 35 months of age, or the deltoid muscle in children from 36 months of age and adults.

Do not administer intravascularly.

INFLUVAC is a colourless clear liquid, in pre-filled single-dose syringes with / without a needle.

Parenteral biological products should be inspected visually for extraneous particulate matter and/or discolouration before administration. If these conditions exist, the product should not be administered.

INFLUVAC should be allowed to reach room temperature (15-25°C) before use.

Shake the pre-filled syringe well to uniformly distribute the suspension before administration.

Remove the needle protection and bleed the syringe of air while holding the needle pointing vertically upward by pressing the plunger in slowly.

For syringes without a needle, remove the cap and attach a needle then bleed the syringe of air while holding the needle pointing vertically upward by pressing the plunger in slowly.

Needles should not be recapped, and the syringe should be disposed of properly.

For information on vaccine administration, see the current Canadian Immunization Guide and

the Health Canada Website.

The patient should be given a permanent personal immunization record. In addition, it is essential that the physician or nurse record the immunization history in the permanent medical record of each patient. Thus, the permanent office record should contain the name of the vaccine, date given, dose, manufacturer and lot number.

5 OVERDOSAGE

Overdosage is unlikely to have any untoward effect.

For management of a suspected drug overdose, contact your regional Poison Control Centre.

6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

To help ensure the traceability of vaccines for patient immunization record-keeping as well as safety monitoring, health professionals should record the time and date of administration, quantity of administered dose (if applicable), anatomical site and route of administration, brand name and generic name of the vaccine, the product lot number and expiry date.

Table – Dosage Forms, Strengths, Composition and Packaging

Route of Administration	Dosage Form / Strength/Composition	Non-medicinal Ingredients
Intramuscular injection or deep subcutaneous injection	0.5 mL suspension for injection in pre-filled syringe with / without needle (glass, type I), containing neuraminidase and 15 mcg haemagglutinin per virus strain. *Pack of 1 or 10.* *Not all pack sizes may be marketed.*	*Excipients* Calcium chloride dihydrate 0.067 mg Disodium phosphate dihydrate 0.67 mg Magnesium chloride hexahydrate 0.05 mg Potassium chloride 0.1 mg Potassium dihydrogen phosphate 0.1 mg Sodium chloride 4.0 mg Water for Injection To 0.5 mL *Manufacturing Process Residuals* May also contain trace amounts of cetyltrimethyl ammonium bromide, chicken protein, egg material, formaldehyde, gentamicin sulphate, hydrocortisone, neomycin sulphate*, polymyxin B sulphate*, polysorbate 80, sodium citrate, sucrose, tylosine tartrate. *Only used if gentamicin cannot be used. If not used, not present.

DESCRIPTION

INFLUVAC (influenza vaccine, surface antigen, inactivated) is a trivalent subunit influenza vaccine. Each 0.5 mL dose contains neuraminidase and 15 mcg of haemagglutinin antigen for each virus strain present in the vaccine. The composition of INFLUVAC is adapted annually to

comply with the World Health Organization (WHO) recommendations (northern hemisphere). The virus strains used in the vaccine for 2025/2026 are:

- an A/Victoria/4897/2022 (H1N1)pdm09-like virus;
- an A/Croatia/10136RV/2023 (H3N2)-like virus;
- a B/Austria/1359417/2021 (B/Victoria lineage)-like virus

INFLUVAC is a colourless clear liquid. INFLUVAC is thimerosal-free, mercury-free, and contains no preservative.

7 WARNINGS AND PRECAUTIONS

General

If INFLUVAC (influenza vaccine, surface antigen, inactivated) is used in persons receiving immunosuppresive therapy, including corticosteroid therapy, the expected immunological response may be diminished. Antibody response in patients with endogenous or iatrogenic immunosuppression may be insufficient.

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.

Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions can occur following, or even before, any vaccination as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.

INFLUVAC should not be administered into the buttocks due to varying amounts of fatty tissue in this region, nor by the intradermal route, since these methods of administration may induce a weaker response.

INFLUVAC must not be administered intravascularly.

Sterile epinephrine HCl solution (1:1000) and other appropriate agents should be made available for immediate use in case of an anaphylactic reaction or if acute hypersensitivity to the vaccine occurs. Health care providers should be familiar with current recommendations for the initial management of anaphylaxis in non-hospital settings, including proper airway management.

Before administration of any vaccine, all appropriate precautions should be taken to prevent adverse reactions. This includes a review of the patient's history with respect to possible hypersensitivity to the vaccine or similar vaccine, determination of previous immunization history, and the presence of any contraindications to immunization, current health status, and a current knowledge of the literature concerning the use of the vaccine under consideration.

Pneumococcal vaccine and influenza vaccine can be given at the same visit but at different sites with separate sterile needles and syringes without an increase in side effects. Whereas influenza vaccine is given annually, pneumococcal vaccine should generally be given only once to adults.

Influenza virus undergoes significant antigenic changes from time to time, so different vaccines are made every year. INFLUVAC, as now constituted, is not effective against all possible strains of influenza virus. Protection is limited to those strains of virus from which the vaccine is prepared or against closely-related strains.

The use of fractional doses in an attempt to reduce the severity of adverse reactions cannot be recommended because there is insufficient evidence on the safety or efficacy of such smaller doses.

As with any vaccine, immunization with INFLUVAC may not protect 100% of susceptible individuals.

INFLUVAC contains sodium, less than 1 mmol (23 mg) per dose and potassium, less than 1 mmol (39 mg) per dose.

Driving and Operating Machinery
INFLUVAC has no or negligible influence on the ability to drive and use machines.

Hematologic
Intramuscular injections should be given with care in persons suffering from coagulation disorders or on anticoagulant therapy because of risk of hemorrhage.

Monitoring and Laboratory Tests
Following influenza vaccination, false positive results in serology tests using the ELISA method to detect antibodies against HIV1, Hepatitis C and especially HTLV1 have been observed. The Western Blot technique disproves the results. The transient false positive reactions could be due to the IgM response to the vaccine.

Neurologic
If Guillain-Barré Syndrome (GBS) has occurred within 6 weeks following previous influenza vaccination, the decision to give INFLUVAC should be based on careful consideration of potential benefits and risks (See 8 ADVERSE REACTIONS).

7.1 Special Populations

7.1.1 Pregnant Women:
Inactivated influenza vaccines, such as INFLUVAC, can be used in all stages of pregnancy. Larger datasets on safety are available for the second and third trimester, compared with the first trimester; however, data from worldwide use of influenza vaccine do not indicate any adverse foetal and maternal outcomes attributable to the vaccine.

7.1.2 Breast Feeding:
Evidence indicates that influenza vaccine is safe for breastfeeding mothers.

7.1.3 Pediatrics:

The safety and efficacy of INFLUVAC in children less than 6 months of age have not been established. (See 14 CLINICAL TRIALS and REFERENCES sections).

7.1.4 Geriatrics:

Studies on healthy elderly subjects showed that INFLUVAC is well tolerated. For more details, see 14 CLINCAL TRIALS.

8 ADVERSE REACTIONS

8.1 Adverse Drug Reaction Overview

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

Local reactions include: redness, swelling, itching, warmth, pain, restriction in arm movement, induration and ecchymosis. The most frequent local reaction is soreness at the injection site lasting up to 2 days in adults but rarely interferes with normal activities. Prophylactic acetaminophen may decrease the frequency of pain at the injection site.

Systemic reactions include: fever, increased sweating, headache, malaise, shivering, myalgia, arthralgia, and fatigue. The most frequent systemic reaction is headache.

Allergic responses to influenza vaccine, which in rare cases could lead to anaphylactic shock, are probably a consequence of hypersensitivity to some vaccine component.

Adverse reactions reported from post marketing surveillance have been observed for INFLUVAC, including allergic reactions in rare cases leading to anaphylactic shock requiring immediate medical help. See 8.5 Post-Market Adverse Reactions.

Neurological disorders, which have been reported in persons after influenza vaccination, include neuritis, encephalomyelitis, febrile convulsions and paresthesia.

Rare cases of systemic vasculitis have been reported in persons after influenza vaccination, but a causal relation has not been established.

8.2 Clinical Trial Adverse Reactions

Clinical trials are conducted under very specific conditions. The adverse reaction rates observed in the clinical trials; therefore, may not reflect the rates observed in practice and should not be compared to the rates in the clinical trials of another drug. Adverse reaction information from clinical trials may be useful in identifying and approximating rates of adverse drug reactions in real-world use.

A total of 1856 patients have been given INFLUVAC with thimerosal or INFLUVAC thimerosal-free in clinical trials. The safety of INFLUVAC was assessed in the following clinical trials: annual strain composition update requirement, including at least 50 adults aged 18-60 years and at least 50 elderly subjects aged 60 years or older, conducted during the period of 1993 to 2002 using INFLUVAC with thimerosal; a study comparing INFLUVAC thimerosal-free

and INFLUVAC with thimerosal; a study with INFLUVAC thimerosal-free; and a study of 52 high-risk children (6 months to 4 years) vaccinated with INFLUVAC with thimerosal.

Safety evaluation (i.e. local and systemic reactogenicity) is performed during the first 3 days following vaccination.

The following undesirable effects have been observed during clinical trials with the following frequencies (Table 1).

Table 1. Summary of adverse events observed during clinical trials

System Organ Class	Common ≥1/100, <1/10
Nervous system disorders	Headache*
Skin and subcutaneous tissue disorders	Sweating*
Musculoskeletal and connective tissue disorders	Myalgia, arthralgia*
General disorders and administration site conditions	Fever, malaise, shivering, fatigue Local reactions: redness, swelling, pain, ecchymosis, induration*.

*These reactions usually disappear within 1-2 days without treatment.

Data on reactogenicity can be found in Table 2.

Table 2. Local and systemic reactions during three days after vaccination with INFLUVAC without thimerosal (n=197)

Total N=197	Adults N=144 (aged 18 – 59 years) % (n)	Elderly N=53 (aged 60 years and over) % (n)
Local reactions		
Redness	17.4 (25)	3.8 (2)
Swelling	11.8 (17)	3.8 (2)
Itching	3.5 (5)	7.5 (4)
Warmth	7.6 (11)	5.7 (3)
Pain on contact	41.7 (60)	5.7 (3)
Continuous pain	3.5 (5)	1.9 (1)
Restriction in arm movement	13.2 (19)	3.8 (2)
Induration	16.7 (24)	1.9 (1)
Ecchymosis	4.2 (6)	3.8 (2)
Systemic reactions		
Increased sweating	3.5 (5)	3.8 (2)
Headache	11.8 (17)	1.9 (1)
Malaise	2.8 (4)	3.8 (2)
Insomnia	3.5 (5)	3.8 (2)
Shivering	2.1 (3)	0.0 (0)

Data from clinical studies with INFLUVAC thimerosal-free show local reactions occurred most frequently the first day after vaccination (37.1%) and declined during the second and third day to 30.5 % and 14.7% respectively. As for the systemic reactions, few participants to the study reported systemic reactions, and the numbers reported remained stable during the first three days (8.6%, 7.6% and 5.1% respectively).

As summarized in Table 3, both local and systemic reactions for both formulations are comparable. The most frequent local reaction was pain on contact (31% and 32% for the thimerosal- containing and thimerosal-free vaccine, respectively), and the most frequent systemic

reaction was headache (11% and 9% for the thimerosal-containing and thimerosal-free vaccine, respectively).

Table 3. Comparison of reactogenicity on thimerosal-free vs. thimerosal-containing INFLUVAC

Measure	Thimerosal-free INFLUVAC n=197 % (n)	thimerosal-containing INFLUVAC n=1692 % (n)
Pain on contact at vaccination site	32% (63)	31% (52)
Headache	9% (18)	11% (19)
Any local symptom	45% (89)	45% (76)
Any systemic symptom	14% (28)	19% (32)
Moderate or severe inconvenience	0% (0)	3% (51)

8.2.1 Clinical Trial Adverse Reactions – Pediatrics

Safety in high-risk children

A clinical study in high-risk children with chronic respiratory or congenital heart disease aged 6 months to 4 years with thimerosal-containing INFLUVAC (Table 4), showed that the vaccine was well tolerated. Following either of the two vaccinations, the incidence of any local (23%) and any systemic reactions (48%) in this particular group was considered comparable with those reported in healthy adults. These children received two separate vaccinations and had the added parameters of loss of appetite, increased crying and irritability. All reactions were recorded in the questionnaire by the parent/guardian (instead of direct reporting). The reactions recorded were relatively minor in nature and were resolved within a few days.

Table 4. Reported vaccine reactions after vaccination (72 hrs) with thimerosal-containing INFLUVAC in high-risk children aged 6 months to 4 years

	Distribution of Reactions after:											
	1st vaccination				2nd vaccination				Any vaccination			
	Yes		No		Yes		No		Yes		No	
	N	%	N	%	N	%	N	%	N	%	N	%
Any Local Reactions	8	15	44	85	7	14	44	86	12	23	40	77
Any Systemic Reactions	17	33	35	67	12	24	39	76	25	48	27	52
Any Reactions	23	44	29	56	14	27	37	73	29	56	23	44

Although a total of fifteen serious adverse events were reported in thirteen of the children (as defined by hospitalization) these were relatively minor events. Due to the underlying chronic respiratory or congenital heart disease in these patients and their young age, it is understandable for their physician to hospitalize them, even in case of minor events which could otherwise be treated at home. Four of the serious adverse events were arranged admissions (for cardiac catheterization (3) or jejunal biopsy).

Only two of these serious adverse events (in two subjects) were thought by the investigators to be possibly related to the vaccine: “Increased cough and diarrhea”, and “Pyrexia, runny nose and cough”.

Safety in asthmatic children

Safety data of INFLUVAC with thimerosal was presented in a recent publication on an investigator initiated placebo controlled study in 6-18 year old asthmatic children, who had taken asthma medication in the year previous to the study. The study was performed during two consecutive influenza seasons (1999-2000 and 2000-2001), but individual patients could only participate for one season. A total of 696 children participated in this study of which 347 were vaccinated with thimerosal-containing INFLUVAC. Influenza-related asthma exacerbations were of comparable number and severity in the group vaccinated with the vaccine and the placebo group. It was found that the duration of the exacerbations was 3 days shorter in the group vaccinated with the INFLUVAC. No serious adverse events to the vaccine were observed in this study.

Safety in children 6 months to 35 months

The safety profile of influenza vaccine in healthy children from 6 months to 35 months of age has been established through clinical data generated from a study using INFLUVAC® TETRA (the quadrivalent formulation). These data are relevant to INFLUVAC because both vaccines are manufactured using the same process and have overlapping compositions. In the Study, INFQ3003, 1005 children were administered the quadrivalent (QIV) influenza vaccine, and compared to 995 children receiving a non-influenza vaccine. The most frequently reported general adverse reactions after vaccination observed in this study in children from 6 to 35 months of age was irritability (30.2%). The most frequently reported local adverse reaction after vaccination was vaccination site pain (22.6%).

Table 5. Incidence of solicited local and systemic reactions[a] in Study Children aged 6 to 35 months after Vaccination with INFLUVAC TETRA compared to Non-influenza vaccine - INFQ3003

	Study INFQ3003			
	INFLUVAC® TETRA		**Non-influenza vaccine (NIV)**	
	N=1005		**N=995**	
	Any Grade	**Grade 3***	**Any Grade**	**Grade 3***
Local				
Pain	22.6%	0.7%	27.0%	0.7%
Redness	11.6%	0.1%	19.6%	0.3%
Swelling	4.3%	--	7.2%	0.2%
Induration	4.4%	--	10.4%	0.1%
Ecchymosis	4.0%	0.1%	4.8%	--
Systemic				
Fever	19.3%	4.8%	18.1%	4.7%
Sweating	12.4%	0.2%	11.5%	0.5%
Irritability	30.2%	1.4%	33.6%	2.0%
Drowsiness	17.5%	0.4%	17.3%	0.8%
Diarrhea/Vomiting	19.8%	0.8%	18.0%	1.2%
Loss of appetite	19.3%	1.1%	21.9%	1.2%

	Study INFQ3003			
	INFLUVAC® TETRA		Non-influenza vaccine (NIV)	
	N=1005		N=995	
	Any Grade	Grade 3*	Any Grade	Grade 3*

*Grade 3:
Vaccination site pain: Cries when arm is moved/ spontaneously painful.
Vaccination site redness, swelling, induration, ecchymosis: > 5 cm
Fever: Temperature (measured by oral or rectal method) > 39.0°C
Sweating: Prevents normal daily activity
Irritability: Crying that cannot be comforted/ prevents normal daily activity
Drowsiness: Prevents normal daily activity
Diarrhea/Vomiting: Prevents normal daily activity
Appetite loss: Not eating at all

N: number of subjects in the safety sample
[a] Local and systemic solicited reactions within 7 days; results shown are the maximum ratings from Day 1 to Day 7.

Local Reactions
Overall, a lower incidence of local reactions within 7 days after vaccination was reported for the QIV group (30.4%) compared with the NIV group (38.1%).

For local reactions where the severity was reported, the majority were mild, with a higher incidence of mild local reactions reported for the QIV group compared with the NIV group for each type of reaction, with the exception of vaccination site ecchymosis. The incidence of severe local reactions was low for each vaccination group, ranging from 0% to 3.1% of cases in each group across the different reaction types.

Local reaction symptoms lasted for 1 to 3 days for the majority of subjects. Symptoms lasted ≥ 7 days for more than 10% of subjects in either vaccination group for the following local reactions, which also noted a difference in the incidence between the vaccination groups: vaccination site induration (6.8% and 11.8% in the QIV and NIV groups, respectively) and vaccination site ecchymosis (25.0% and 12.8%, respectively). For the remaining local reactions, a similar proportion of subjects had a duration of ≥ 7 days between the QIV and NIV groups.

Overall, there was no notable difference in the reactogenicity between the first and second vaccinations for both vaccination groups in terms of severity/duration, with the exception of vaccination site pain, which was more severe and lasted longer for a higher proportion of subjects after the first vaccination compared with after the second vaccination.

Systemic Reactions
Overall, a similar proportion of subjects in the QIV and NIV groups (51.4%) and NIV (52.5%) had any systemic reaction within 7 days after vaccination.

For systemic reactions where the severity was reported, the majority were mild to moderate in severity for both the QIV and NIV groups. A similar proportion of subjects with severe systemic reactions of each type was reported between the QIV and NIV groups for the overall population.

Systemic reaction symptoms lasted for 1 to 3 days for the majority of subjects. Symptoms lasted ≥ 7 days for more than 10% of subjects in either vaccination group for the following systemic reactions: irritability (10.3% and 12.1% in the QIV and NIV groups, respectively), sweating (8.1% and 14.2%), diarrhea/vomiting (8.6% and 13.0%), and loss of appetite (14.5% and 11.6%). For the majority of individual systemic reactions, a similar proportion of subjects had reactions lasting ≥ 7 days between the QIV and NIV groups.

Overall, reactogenicity after the second vaccination was lower compared with the first vaccination in both

the QIV and NIV groups in terms of severity/duration for most of the individual systemic reactions.

8.5 Post-Market Adverse Drug Reactions

Because post-market reporting of adverse reactions is voluntary and from a population of uncertain size, it is not always possible to reliably estimate the frequency of these reactions or establish a causal relationship to drug exposure. Evaluation and interpretation of these post marketing reactions is confounded by underlying diagnosis, concomitant medications, preexisting conditions, and inherent limitations of passive surveillance.

Adverse reactions reported from post marketing surveillance are, in addition to the reactions which have also been observed during clinical trials, the following:

Blood and lymphatic system disorders:
Transient thrombocytopenia, transient lymphadenopathy

Immune system disorders:
Allergic reactions, in rare cases leading to shock, angioedema

Nervous system disorders:
Neuralgia, paraesthesia, febrile convulsions, neurological disorders, such as encephalomyelitis, neuritis and Guillain Barré syndrome

Guillain-Barré Syndrome (GBS) occurred in adults in association with the 1976 swine influenza vaccine, and evidence favours the existence of a causal relation between the vaccine and GBS during that season. In an extensive review of studies since 1976, the United States Institute of Medicine concluded that the evidence is inadequate to accept or reject a causal relation between GBS in adults and influenza vaccines administered after the swine influenza vaccine program in 1976.

In Canada the background incidence of GBS was estimated at just over 20 cases per million population in a study done in Ontario and Quebec. A variety of infectious agents, such as *Campylobacter jejuni*, have been associated with GBS. It is not known whether influenza virus infection itself is associated with GBS. Neither is it known whether influenza vaccination is causally associated with increased risk of recurrent GBS in persons with a previous history of GBS. Avoiding subsequent influenza vaccination of persons known to have developed GBS within 6 to 8 weeks of a previous influenza vaccination appears prudent at this time. The reporting rate of GBS associated with INFLUVAC is concluded to remain within the expected back-ground incidence.

Influenza vaccine is not known to predispose to Reye's Syndrome.

Oculorespiratory Syndrome (ORS) has been reported sporadically in Canada, US and Europe following influenza immunization. Starting in the 2000/2001 season, ORS is defined as the onset of bilateral red eyes and/or respiratory symptoms (cough, wheeze, chest tightness, difficulty breathing, difficulty swallowing, hoarseness or sore throat) and/or facial swelling occurring within 24 hours of influenza immunization. The pathophysiologic mechanism underlying ORS remains unknown.

After the 2000-2001 influenza season, fewer ORS cases have been reported to Health Canada. Please refer to the *Canadian Immunization Guide* for further details about administration of vaccine and management of adverse events.

Vascular disorders:
Vasculitis associated in very rare cases with transient renal involvement.

Skin and subcutaneous tissue disorders:
Generalized skin reactions including pruritus, urticaria or non-specific rash.

Physicians, nurses and pharmacists should report any immediate adverse reactions arising from any vaccination, or following shortly thereafter, in accordance with local requirements and to the manufacturer: Drug Safety, BGP Pharma ULC, 85 Advance Rd., Etobicoke, ON M8Z 2S6 Canada. Telephone: 1-844-596-9526.

9 DRUG INTERACTIONS

9.2 Drug Interaction Overview
No interaction between INFLUVAC (influenza vaccine, surface antigen, inactivated) and other vaccines or medication are known.

9.4 Drug-Drug Interactions
Interactions with other drugs have not been established. INFLUVAC may be given at the same time as other vaccines. 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.

Theophylline and Anticoagulants
Influenza vaccine can inhibit the clearance of theophylline and anticoagulants such as warfarin. However, clinical studies have not shown any adverse effects attributable to these drugs in people receiving influenza vaccine.

9.5 Drug-Food Interactions
Interactions with food have not been established.

9.6 Drug-Herb Interactions
Interactions with herbal products have not been established.

9.7 Drug-Laboratory Interactions
Following influenza vaccination, false positive results in serology tests using the ELISA method to detect antibodies against HIV1, Hepatitis C and especially HTLV1 have been observed. The Western Blot technique disproves the results. The transient false positive reactions could be due to the IgM response by the vaccine.

10 CLINICAL PHARMACOLOGY

10.1 Mechanism of Action

INFLUVAC (influenza vaccine, surface antigen, inactivated) is an egg-grown, inactivated influenza virus subunit, trivalent vaccine based on isolated surface antigens of A and B strains of myxovirus influenza. The inoculation of antigen prepared from inactivated influenza virus stimulates the production of specific antibodies. Protection is afforded only against those strains of virus from which the vaccine is prepared or closely related strains.

Influenza A viruses are classified into subtypes on the basis of 2 surface antigens: haemagglutinin (H) and neuraminidase (N). Three subtypes of haemagglutinin (H1, H2, H3) and 2 subtypes of neuraminidase (N1, N2) are recognized among influenza A viruses that have caused widespread human disease. Immunity to these antigens, especially to the haemagglutinin, reduces the likelihood of infection and lessens the severity of disease if infection occurs. Infection with a virus of one subtype confers little or no protection against viruses of other subtypes. Antigenic variation over time within a subtype may be so marked that infection or vaccination with one strain may not induce immunity to distantly related strains of the same subtype. Although influenza B viruses have shown more antigenic stability than influenza A viruses, antigenic variation does occur. For these reasons, major epidemics of respiratory disease caused by variants of influenza still occur. The antigenic characteristics of current and emerging influenza virus strains provide the basis for selecting the virus strains included in each year's vaccine.

Each year's influenza vaccine contains 3 virus strains representing the influenza viruses that are likely to be circulating in Canada on the basis of the recommendation from the World Health Organization for the northern hemisphere.

10.2 Pharmacodynamics

Protective antibody levels are generally obtained within 2 to 3 weeks after vaccination. See 14 CLINICAL TRIALS, 14.2 Study Results.

10.3 Pharmacokinetics

As this is a vaccine product, pharmacokinetic studies are not applicable.

Duration of Effect

Protective antibody titres generally last for at least 6 months and may last up to one year or longer. New influenza vaccines are produced each year according to the WHO recommended composition. Patients vaccinated a short time before the start of the expected influenza activity (November in the Northern Hemisphere) may therefore be expected to be protected for influenza infections or its complications during the whole influenza season (November to April).

Serological data over a 52-week period since vaccination in healthy adult subjects aged 18 to 60 years showed a substantial decrease in antibody titres, as is to be expected for Influenza vaccines. Still the 52-week GMT values are markedly elevated as compared to the pre-vaccination values. The observed decline in GMT values over a one year period was approximately 50-70% for both strains. The sustained levels of protective antibody titres are in line with the expectation of protection during an influenza season up to 6 months after vaccination.

11 STORAGE AND STABILITY

INFLUVAC (influenza vaccine, surface antigen, inactivated) should be stored 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 vaccine after expiration date as stated on the label.

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

12 SPECIAL HANDLING INSTRUCTIONS

INFLUVAC (influenza vaccine, surface antigen, inactivated) should be allowed 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. Inspect visually prior to administration.

Any unused product or waste material should be disposed of in accordance with local requirements.

PART II: SCIENTIFIC INFORMATION

13 PHARMACEUTICAL INFORMATION

Drug Substance

Proper name: Trivalent Influenza virus subunit vaccine (surface antigen, inactivated).

Chemical name: Monovalent Bulk containing inactivated haemagglutinin and neuraminidase surface antigens of WHO recommended strains of influenza virus.

Physiochemical properties: The Monovalent Bulk is a clear to slightly opalescent liquid. The pH of the Monovalent Bulk is in the range 6.9 to 7.5.

Pharmaceutical standard: Ph. Eur.

Product Characteristics

This vaccine complies with the WHO recommendations (northern hemisphere) for the 2025-2026 season. The active substances are:

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

- an A/Victoria/4897/2022 (H1N1) pdm09-like strain (A/Victoria/4897/2022, IVR-238)
- an A/Croatia/10136RV/2023 (H3N2)-like strain (A/Croatia/10136RV/2023, X-425A)
- a B/Austria/1359417/2021 (B/Victoria lineage)-like strain (B/Austria/1359417/2021, BVR-26)

The virus strain is supplied as a primary seed virus by the NIBSC (National Institute for Biological Standards and Control, Potters Bar, UK), or by another designated WHO laboratory. The primary seed virus is propagated in embryonated SPF (specific pathogen-free) hens' eggs to generate a master seed virus (MSV). The working seed virus (WSV) is generated by the propagation of the MSV in embryonated SPF hens' eggs.

The WSV is diluted to a seed suspension and then inoculated in embryonated eggs. The inoculated eggs are incubated for approximately 3 days. After incubation, the eggs are cooled to 5 ± 3°C for 12 - 48 hours.

The allantoic fluid is harvested from the eggs and clarified using a centrifuge to remove cell and egg debris. The clarified allantoic fluid of the single harvest of a strain is separated in a zonal gradient centrifuge (0-60% sucrose). The virus containing fractions with approximately 47 to 35% m/m of sucrose are collected and inactivated by formaldehyde treatment in two stages, first for 18 hours to 3 days and secondly for 4 to 10 days. The inactivated fractions are pooled, filtered and diluted with PBS. The sucrose and formaldehyde is removed by ultrafiltration. The haemagglutinin and neuraminidase are solubilised by the addition of Polysorbate 80 and CTAB.

The non-solubilised remainders of the virus particles are removed by centrifugation.
The CTAB and the Polysorbate 80 are removed from the supernatant by adsorption to an adequate quantity of Amberlite XAD-4 resin. After adsorption of the detergents, the Amberlite resin is removed by filtration. PBS is added and the final suspension is sterilised by filtration which is the Monovalent Bulk vaccine.

The manufacture of the drug product (=final lot) involves blending three monovalent bulks, and diluting the drug substance with buffers to produce the final (=trivalent) bulk. The final bulk is filled into single-dose syringes, using an Isolator filling machine to produce the final product.

14 CLINICAL TRIALS

14.1 Trial Design and Study demographics

Data analysis includes 24 vaccination studies conducted with INFLUVAC (influenza vaccine, surface antigen, inactivated) with thimerosal during the period between 1993-2002, study comparing INFLUVAC (influenza vaccine, surface antigen, inactivated) thimerosal-free and INFLUVAC with thimerosal, and an annual update study with INFLUVAC thimerosal-free. An overview of exposure and demographic data is given in Tables 6-7. A total of 1659 subjects of 6 months and older were vaccinated with standard doses of INFLUVAC with thimerosal: 1010 healthy adults (18 – 60 years), 597 healthy elderly (>60 years), 85 healthy adults aged 18 – 60 years in a comparative trial and 52 high-risk children (6 months to 4 years) (Table 6). A total of 197 subjects of 18 years and older were vaccinated with standard doses of INFLUVAC thimerosal-free (Table 6): 84 subjects aged 18 – 60 years in a comparative trial, 60 healthy subjects aged 18 – 60 years in an annual strain update study and 53 healthy elderly aged 60 years and over in an annual strain update study.

Additionally, a vaccine efficacy study in children aged 6 to 35 months was conducted across Europe and Asia over three influenza seasons (NH 2017/2018, NH 2018/2019, and SH 2019). 1005 participants received INFLUVAC TETRA (quadrivalent influenza vaccine (QIV formulation)) and 995 received a non-influenza control vaccine (NIV). Participants were administered two 0.5 mL doses of either QIV or NIV on Day 1 and Day 29. The study included 50.6% female and 49.4% male participants, with 98% identified as either White (73.9%) or Asian (24.1%). An overview of exposure and demographic data is given in Table 8.

Table 6. Demographic Data on INFLUVAC thimerosal-free

Study number	Trial Design	Dosage, route of administration and duration	Number of vaccinees	Mean age (range)	Gender N_{male}/N_{female}
25[1]	Double blind, randomized, parallel groups	0.5 mL pre-filled syringe containing neuraminidase and 15 mcg haemagglutinin per viral strain, intramuscular or deep subcutaneous injection, and 3 weeks	84	38.3 (18-59)	44/40
26[2] (adults)	Open, Baseline controlled	0.5 mL pre-filled syringe containing neuraminidase and 15 mcg haemagglutinin per viral strain, intramuscular or deep subcutaneous injection, and 3 weeks	60	29.8 (18-59)	16/44
26[2] (elderly)	Open, Baseline controlled	0.5 mL pre-filled syringe containing neuraminidase and 15 mcg haemagglutinin per viral strain, intramuscular or deep subcutaneous injection, and 3 weeks	53	68.2 (60-79)	26/27

[1] Comparative, double blind parallel study with thimerosal-free INFLUVAC and the standard INFLUVAC. Here, only the data for the thimerosal-free INFLUVAC were included.
[2] Previously separate annual update studies were performed for (young) adults (≥18 and ≤60 years of age) and elderly subjects (>60 years); in recent annual update studies both age groups participate in the same protocol.
[3] In 2003 no separate annual update study was necessary since the composition of the strains had not changed since the previous Influenza season.

Table 7. Demographic Data on INFLUVAC thimerosal-containing INFLUVAC in High-Risk children aged 6 months to 4 years

Study number	Trial Design	Dosage, route of administration and duration	Number of vaccinees	Mean age (range)	Gender N_{male}/N_{female}
27	Open, Baseline controlled	0.25 mL pre-filled syringe containing neuraminidase and 15 mcg haemagglutinin per viral strain, intramuscular or deep subcutaneous injection, and 4 weeks	52 [1]	19.5 months (6-48months)	25/27

[1] 52 children that started with the study, of which 51 actually completed the entire study period.

Table 8. Demographic Data on INFLUVAC TETRA in children aged 6 months to 35 months in prophylaxis of influenza

Study #	Study design	Dosage, route of administration and duration	Study subjects (n*)	Mean age (Range)	Sex
INFQ3003	Randomized, observer-blind, non-influenza vaccine (NIV) comparator-controlled, parallel-group study	0.5 mL, intramuscular two injections	2,007	19.5 months (range 6 to 35 months old)	QIV[#]: 48.8% male NIV[$]: 50.0% male

* Total number of randomized subjects.
[#] Quadrivalent Influenza vaccine (Influvac Tetra)
[$] Non-Influenza vaccine

14.2 Study results

See, 14.4 Immunogenicity.

14.4 Immunogenicity

Immunogenicity data consisted of pre- and post-vaccination titres per subject and vaccine strain, determined in duplicate. After logarithmic transformation, immunogenicity parameters as requested by the CHMP (Table 9) were calculated per study: mean fold increase (MFI), numbers of subjects exceeding a protective titre of 40 after vaccination (seroprotection (SP_{post})), and numbers of at least fourfold titre rise (seroconversion (SC)). Moreover, pre- and post-vaccination geometric mean titre (GMT), and numbers of subjects exceeding a protective titre of 40 prior to vaccination (SP_{pre}), were determined.

Table 9. Criteria for assessment of influenza vaccines, according to the CHMP

Age class	Serological parameter	Criteria
Adults 18 to 60 years of age	MFI	**> 2.5**
	SP (% of subjects exceeding a titre of 40)	**> 70%**
	SC (% of subjects with seroconversion or at least 4-fold titre rise)	**> 40%**
Adults ≥60 years of age (Elderly)	MFI	**> 2.0**
	SP (% of subjects exceeding a titre of 40)	**> 60%**
	SC (% of subjects with seroconversion or at least 4-fold titre rise)	**> 30%**

In all 26 studies in young and elderly adults the current CHMP requirement for sufficient immunogenicity (meeting at least one of the criteria for each of the three strains) was met. In fact, in 24 of the 26 studies all three criteria were met for all strains in the vaccine. The absence of thimerosal did not affect the immunogenicity of the vaccine, as all three CHMP criteria for all three strains were met and no differences were found compared to the thimerosal-containing product.

Since there are no CHMP-criteria for children, the CHMP criteria for adult subjects were used to evaluate the data from high-risk children. The CHMP-requirement for immunogenicity was met in this specific population of young children at risk.

Tables 10 and 11 show the serological parameters for all studies in adults/elderly, according to (sub)type. The serological response as measured by a number of parameters was excellent in most cases, which confirms previous observations.

For INFLUVAC with thimerosal all of the 74 MFI-values and SC-values exceeded the CHMP -criteria, as well as 71 of 74 SP_{post}-values. In 44 cases, SP_{post}-values were even greater than 90%. In three studies, SP_{post}-values of some strains did not reach the value as required by the CHMP: Study nr. 2 (elderly) for virus strains A-H_1N_1 and B and Study nr. 9 (young adults) for virus strain A-H_3N_2. The overall CHMP requirement was still met in these three studies (i.e. the other CHMP criteria for these strains were compliant). For the INFLUVAC thimerosal-free, the CHMP criteria for MFI, SC and SP_{post} were met in all three strains used.

The comparative study analysed the effect of the absence of the preservative thimerosal on the immunogenicity of the vaccine. The results obtained in the study (Tables 10 and 11) show that the absence of the preservative does not have any effect on the efficacy of the vaccine.

In the study with high-risk children aged 6 months to 4 years (Table 12), the vaccine induced a strong immunogenic response against all three haemagglutinin antigens. In fact, the CHMP - requirement applicable to adults/elderly was also met for this specific group.

Table 10. Serological parameters for the INFLUVAC thimerosal-free - Pre- and post-GMT, MFI, Pre- and post-SP, and SC

Studynr.	Subtype	N	GMT_{pre}*		GMT_{post}*		MFI*		SP_{pre}*		SP_{post}*		SC*	
25[1]	A-H_3N_2	84	13.4	(10.4 – 17.3)	254.8	(207.0 – 313.7)	19.0	(14.1 – 25.7)	23	(14 – 32)	98	(94 – 100)	85	(77 – 92)
	A-H_1N_1	84	5.8	(5.1 – 6.6)	131.2	(99.7 – 172.5)	22.7	(17.2 – 29.9)	4	(0 – 8)	86	(78 – 93)	82	(74 – 90)
	B	84	5.1	(4.9 – 5.4)	71.2	(53.9 – 94.0)	13.9	(10.6 – 18.3)	0		77	(68 – 86)	77	(68 – 86)
26[2]	A-H_3N_2	59[2]	30.9	(21.3 – 44.8)	385.5	(337.4 – 440.4)	12.5	(8.3 – 18.8)	58	(44 – 70)	100	(94 – 100)	75	(62 – 85)
adults	A-H_1N_1	59[2]	7.5	(5.8 – 9.6)	307.5	(263.1 – 359.5)	41.0	(30.7 – 54.9)	12	(5 – 23)	100	(94 – 100)	93	(84 – 98)
	B	59[2]	14.5	(10.6 – 19.8)	250.5	(217.3 – 288.9)	17.3	(13.2 – 22.7)	34	(22 – 47)	100	(94 – 100)	97	(88 – 100)
26[2]	A-H_3N_2	53	34.5	(22.6 – 52.6)	262.2	(205.4 – 334.8)	7.6	(5.0 – 11.5)	53	(39 – 67)	96	(87 – 100)	64	(50 – 77)
elderly	A-H_1N_1	53	13.5	(9.8 – 18.5)	106.8	(84.7 – 134.7)	7.9	(5.3 – 11.9)	32	(20 – 46)	96	(87 – 100)	62	(48 – 75)
	B	53	20.9	(14.8 – 29.6)	182.9	(152.8 – 219.0)	8.7	(6.1 – 12.5)	42	(28 – 56)	98	(90 – 100)	75	(62 – 86)

* Geometric means and 95% confidence intervals;
[1] Subjects vaccinated with INFLUVAC thimerosal-free in study S201.3.118
[2] The annual update 2004 (protocol S201.3.120) studied adults and elderly populations in one protocol. From 60 subjects 18-60 years of age, one subject's data were excluded for serology sampling because of an intercurrent infection during the study.
† Proportion (x 100%) and 95% confidence intervals
GMT = Geometric Mean Titre; MFI = Mean Fold Increase; SP = Seroprotection; SC = Seroconversion

Table 11. Serological parameters for the INFLUVAC thimerosal-free and INFLUVAC thimerosal containing- Pre- and post-GMT, MFI, Pre- and post-SP, and SC

Studynr.	Subtype	N	GMT_{pre}*		GMT_{post}*		MFI*		SP_{pre}*		SP_{post}*		SC*	
25[1]	A-H_3N_2	84	13.4	(10.4 – 17.3)	254.8	(207.0 – 313.7)	19.0	(14.1 – 25.7)	23	(14 – 32)	98	(94 – 100)	85	(77 – 92)
	A-H_1N_1	84	5.8	(5.1 – 6.6)	131.2	(99.7 – 172.5)	22.7	(17.2 – 29.9)	4	(0 – 8)	86	(78 – 93)	82	(74 – 90)
	B	84	5.1	(4.9 – 5.4)	71.2	(53.9 – 94.0)	13.9	(10.6 – 18.3)	0		77	(68 – 86)	77	(68 – 86)
25**	A-H_3N_2	83	18.6	(14.1– 24.5)	231.5	(185.8 – 288.4)	12.4	(8.8 – 17.6)	35	(25 – 45)	98	(94 – 100)	70	(60 – 80)
	A-H_1N_1	83	5.9	(5.2 – 6.6)	107.9	(82.1 – 142.0)	18.3	(13.9 – 24.2)	4	(0 – 8)	84	(77 – 92)	82	(74 – 90)
	B	83	5.9	(5.3 – 6.6)	61.3	(45.1 – 83.5)	10.3	(7.6 – 14.2)	2	(0 – 6)	72	(63 – 82)	67	(57 – 78)

[1] Subjects vaccinated with INFLUVAC thimerosal-free in study S201.3.118
** Subjects vaccinated with thimerosal-containing INFLUVAC in study S201.3.118
GMT = Geometric Mean Titre; MFI = Mean Fold Increase; SP = Seroprotection; SC = Seroconversion

Table 12. Serological parameters for the thimerosal-containing INFLUVAC - Pre- and post-GMT, MFI, Pre- and post-SP, and SC; high-risk children aged 6 months to 4 years

Studynr.	Subtype	N	GMT_{pre}*		GMT_{post}*		MFI*		SP_{pre}†	SP_{post}†	SC†
27	A-H_3N_2	51	13.1	(8.7 – 19.6)	76.2	(40.9 – 142.2)	5.8	(4.3 – 7.9)	25 (14 – 40)	55** (40 – 69)	55 (40 – 69)
	A-H_1N_1	51	5.2	(4.8 – 5.6)	56.0	(38.1 – 82.3)	10.8	(7.5 – 15.4)	2 (0 – 11)	71 (56 – 83)	71 (56 – 81)
	B	51	6.2	(5.1 – 7.6)	65.3	(44.3 – 96.4)	10.5	(7.4 – 14.8)	6 (1 – 17)	71 (56 – 83)	69 (54 – 81)

* Geometric means and 95% confidence intervals;
† Proportion (x 100%) and 95% confidence intervals
** Compared to the CPMP criteria for adults and elderly subjects, postvaccination seroprotection levels were met for the A-H_1N_1 and B strains. The A-H_3N_2 strain showed a somewhat lower response though still offering protection to a large group of vaccinees.
GMT = Geometric Mean Titre; MFI = Mean Fold Increase; SP = Seroprotection; SC = Seroconversion

Efficacy of INFLUVAC in children 6 - 35 months of age:

The efficacy of influenza vaccine in the 6 to 35-month age group was evaluated based on the use of the QIV formulation in a randomized, observer-blind, non-influenza vaccine-controlled study (INFQ3003) conducted during 3 influenza seasons 2017 to 2019 in Europe and Asia. The study was stratified by the age groups 6-11, 12-18, 19-24, and 25-35 months. Healthy subjects aged 6 - 35 months received two doses of INFLUVAC® TETRA (N=1005) or non-influenza control vaccine (N=995) approximately 28 days apart. The efficacy of INFLUVAC® TETRA was assessed for the prevention of reverse transcription polymerase chain reaction (RT-PCR) confirmed influenza A and/or B disease due to any influenza strain. All RT-PCR-positive specimens were further tested for viability in cell culture and to determine whether the circulating viral strains matched those in the vaccine. The vaccine efficacy of INFLUVAC® TETRA in the prevention of symptomatic influenza infection compared with a non-influenza vaccine in children aged 6 months to 35 months was demonstrated with an overall vaccine efficacy of 54% for any strain and 68% for the strains contained in the vaccine (See Table 13).:

Table 13. Efficacy in children 6 – 35 months of age after Vaccination with INFLUVAC TETRA compared to Non-influenza vaccine

	INFLUVAC® TETRA N=1005	**Non-influenza control-vaccine N=995**	**Vaccine efficacy (95% CI)**
Laboratory-confirmed influenza caused by:	n	n	
- Any influenza A or B strain	59	117	0.54 (0.37 - 0.66)
- Culture confirmed vaccine matching strains	19	56	0.68 (0.45 - 0.81)

Vaccine efficacy (VE) for the prevention of symptomatic influenza infection due to any circulating seasonal influenza strain is defined as 1–RR, with RR the relative risk of influenza infection for QIV vaccinated children. The relative risk is estimated by the hazard ratio, using Cox's proportional hazards model. The 95% confidence interval for VE is estimated using 1 minus the lower and upper bound of the 95% confidence interval of the hazard ratio. Age groups (6-11 months, 12-18 months, 19-24 months, 25-35 months and 6-24 months), cohorts and country as well as vaccine group (QIV or NIV) are factors in the Cox proportional hazards model.

N=number of subjects vaccinated
n=number of influenza cases
CI=confidence interval

The immunogenicity of the influenza vaccine was evaluated in terms of HI Geometric mean antibody titer approximately 28 days after the second vaccination across 3 influenza seasons.

Pediatric Studies

The pediatric indication for INFLUVAC is supported by studies published between 1997 and 2019 in healthy and high-risk children aged 6 months to 17 years of age.

15 MICROBIOLOGY

No microbiological information is required for this drug product.

16 NON-CLINICAL TOXICOLOGY

General Toxicology:

Repeated dose toxicity was investigated in male and female rabbits using a seasonal monovalent (trivalent) vaccine, which also included an adjuvanted influenza vaccine. General conclusion of this study is that the seasonal influenza vaccine used in this study did not show any systemic toxicity, when given as 3 subsequent vaccinations over the course of 4 weeks.

Reproductive and Developmental Toxicology: Reproductive and developmental toxicity was investigated using trivalent seasonal vaccine. No unusual results were obtained, and the safety of the vaccine in this respect was confirmed.

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

INFLUVAC®

Trivalent influenza vaccine, surface antigen, inactivated suspension for injection in pre-filled syringes

Read this carefully before you receive INFLUVAC. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about INFLUVAC.

What is INFLUVAC used for?

INFLUVAC is a vaccine used to prevent adults and children 6 months of age and older from developing influenza (the flu).

How does INFLUVAC work?

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.

What are the ingredients in INFLUVAC?

Medicinal ingredient: INFLUVAC complies with the World Health Organization (WHO) recommendations for vaccination in the northern hemisphere for the 2025/2026 season.

Each 0.5 mL pre-filled syringe for injection contains neuraminidase and 15 mcg haemagglutinin of the following virus strains:
- an A/Victoria/4897/2022 (H1N1) pdm09-like virus;
- an A/Croatia/10136RV/2023 (H3N2)-like virus; and
- a B/Austria/1359417/2021 (B/Victoria lineage)-like virus

Non-Medicinal Ingredients: Calcium chloride dihydrate, disodium phosphate dihydrate, magnesium chloride hexahydrate, potassium chloride, potassium dihydrogen phosphate, sodium chloride, water for injection and may also contain trace amounts of cetyltrimethyl ammonium bromide, chicken protein, egg material, formaldehyde, gentamicin sulphate (or neomycin sulphate, polymyxin B sulphate), hydrocortisone, polysorbate 80, sodium citrate, sucrose and tylosine tartrate.

INFLUVAC comes in the following dosage form:

A 0.5 mL pre-filled syringe.

Do not use INFLUVAC if:

- 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 DOSAGE FORMS, STRENGTHS, 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.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take INFLUVAC. Talk about any health conditions or problems you may have, including if:

- 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 experienced any health problems
- you are pregnant
- you are currently on any medication (i.e., immunosuppressants, theophylline, anticoagulants such as warfarin).
- You have experienced fainting, feeling faint or other stress related reactions with a previous injection.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take INFLUVAC:

INFLUVAC should only be given by a health care professional.

Usual Dose:
Adults: 0.5 mL, single dose.

children from 6 months of age: 0.5 mL. For children less than 9 years of age, who have not previously been vaccinated, a second dose should be given after an interval of at least 4 weeks.

The safety and efficacy of INFLUVAC have not been established in infants less than 6 months of age.

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.

If you think you, or a person you are caring for, have taken too much INFLUVAC, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using INFLUVAC?

These are not all the possible side effects you may have when taking INFLUVAC. If you experience any side effects not listed here, tell your healthcare professional.

Occasionally people have side effects with influenza vaccines. The most common of these are fever, feeling unwell, irritability (in children 6 months of age to 5 years old), 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 1-3 days.

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.

Serious side effects and what to do about them			
Symptom / effect	**Talk with your healthcare professional**		**Stop taking drug and get immediate medical help**
	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	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Suspected Side Effects for Vaccines

For the general public: Should you experience a side effect following immunization, please report it to your healthcare professional.

Should you require information related to the management of the side effect, please contact your healthcare professional. The Public Health Agency of Canada, Health Canada and BGP Pharma ULC cannot provide medical advice.

For healthcare professionals: If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (http://www.phac-aspc.gc.ca/im/aefi-essi-form-eng.php) and send it to your local Health Unit.

Storage:

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 2025/2026 influenza virus.

Keep out of reach and sight of children.

If you want more information about INFLUVAC:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html; the manufacturer's website www.viatris.ca, or by calling 1-844-596-9526.
- This information is current up to the time of the last revision date shown below, but more current information may be available from the manufacturer.

This leaflet was prepared by BGP Pharma ULC, Etobicoke, Ontario, M8Z 2S6

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