PRODUCT MONOGRAPH

VAXIGRIP®

Inactivated Influenza Vaccine Trivalent Types A and B (Split Virion)

Suspension for Injection

Active Immunizing Agent for the Prevention of Influenza

ATC Code: J07B B

Manufactured by:
Sanofi Pasteur SA
Lyon, France

Date of Approval:
April 2009

Distributed by:
Sanofi Pasteur Limited
Toronto, Ontario, Canada

Control Number 128614

Table of Contents

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PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Clinically Relevant Nonmedicinal Ingredients
Intramuscular injection.	Suspension for injection. Each 0.5 mL dose is formulated to contain: 15 µg of hemagglutinin (HA) for each strain listed below. Each 0.25 mL dose is formulated to contain: 7.5 µg of hemagglutinin (HA) for each strain listed below. For a complete listing see DOSAGE FORMS, COMPOSITION AND PACKAGING section.	thimerosal* formaldehyde Triton® X-100† neomycin

* Multidose presentation only.

† Triton® X-100 – a registered trademark of Union Carbide, Co.

DESCRIPTION

VAXIGRIP® [Inactivated Influenza Vaccine Trivalent Types A and B (Split Virion)] for intramuscular use, is a sterile suspension containing 3 strains of influenza virus cultivated on embryonated eggs, concentrated, purified by zonal centrifugation in a sucrose gradient, split by Triton® X-100, inactivated by formaldehyde and then diluted in phosphate buffered saline solution. The type and amount of viral antigens contained in VAXIGRIP® conform to the current requirements of the World Health Organization (WHO). (1) The strains for the 2009-2010 season are: A/Brisbane/59/2007 (H1N1)-like strain [A/Brisbane/59/2007 (IVR-148)], A/Brisbane/10/2007 (H3N2)-like strain [A/Uruguay/716/2007 (NYMC X-175C)] and B/Brisbane/60/2008-like strain (B/Brisbane/60/2008).

INDICATIONS AND CLINICAL USE

VAXIGRIP® is indicated for active immunization against influenza caused by influenza virus in adults and children 6 months of age and older.

Influenza vaccine may be administered to any child ≥6 months of age, adolescent, or adult in whom contraindications are not present. (2)

Although the current influenza vaccine can contain one or more of the antigens administered in previous years, annual vaccination using the current vaccine is necessary because immunity declines in the year following vaccination.

The national goal of influenza immunization programs is to prevent serious illness caused by influenza and its complications, including death. The National Advisory Committee on Immunization (NACI) therefore recommends that immunization programs target vaccine delivery, as a priority, to those persons at high risk of influenza-related complications, those capable of transmitting influenza to individuals at high risk of complications, and those who provide essential community services; however, NACI encourages annual vaccine for all Canadians. (3)

Influenza vaccination is particularly recommended for persons in the following categories: (3)

Persons at High Risk of Influenza-Related Complications

NACI states that vaccination of persons at high risk each year before the influenza season is currently the most effective measure for reducing the impact of influenza. (3)

- **Adults and children with selected chronic health conditions.** These include cardiac or pulmonary disorders (including bronchopulmonary dysplasia, cystic fibrosis and asthma), diabetes mellitus and other metabolic diseases, cancer, immunodeficiency, immunosuppression (due to underlying disease including HIV (2) and/or therapy), renal disease, anemia or hemoglobinopathy and conditions that compromise the management of respiratory secretions and are associated with an increased risk of aspiration. Children and adolescents (aged 6 months to 18 years) with conditions treated for long periods with acetylsalicylic acid. (3)
- **Persons of any age who are residents of nursing homes and other chronic care facilities.** (3)
- **Persons 65 years of age and over.** (3) (4)
- **Pregnant women.** (3) (See WARNINGS AND PRECAUTIONS, Pregnant Women.)
- **Healthy children aged 6 to 23 months**. (2) (3)

Persons Capable of Transmitting Influenza to Those at High Risk

Persons who are potentially capable of transmitting influenza to those at high risk should receive annual immunization, regardless of whether the high-risk person(s) has been immunized. (3)

- **Health-care and other care providers** in facilities and community settings including regular visitors, emergency response workers, those who have contact with residents of continuing care facilities or residences and those who provide home care for persons in high-risk groups. (3)
- **Those who provide services within closed or relatively closed settings to persons at high risk** (e.g., crew on ships). (3)
- **Household contacts (adults and children) of persons at high risk of influenza complications, whether or not they have been immunized.** This group includes household contacts of children <6 months of age (who are at high risk of complications from influenza but for whom there is no available effective vaccine), children aged 6 to 23 months and pregnant women. (3)

- **Those providing regular child care** to children <24 months of age whether in or out of the home. (3)
- **Persons who provide essential community services.** Vaccination for these persons should be encouraged in order to minimize the disruption of routine activities during annual epidemics. (2) (3)
- **Persons in direct contact with poultry infected with avian influenza during culling operations.** The relevant individuals include those performing the cull as well as others (such as supervising veterinarians and inspectors) who may be directly exposed to the avian virus. (3)

Immunization of Healthy Persons

- **Immunization of healthy persons aged 2 to 64 years.** Persons in this group should be encouraged to receive the vaccine, even if they are not in one of the aforementioned priority groups. (3)
- **Employers and their employees** should consider yearly influenza immunization for healthy working adults; as this has been shown to decrease work absenteeism from respiratory and other illnesses. (3)
- **Students or other persons in institutional settings** (e.g., those who reside in dormitories) should be encouraged to receive vaccine to minimize disruption of routine activities during epidemics. (2)
- **Travellers.** Persons with selected chronic medical conditions should be immunized as previously discussed. Healthy persons should be encouraged to receive vaccine. (3)

Vaccine should be offered to both children and adults up to and even after influenza virus activity is documented in a community. (2) (3)

CONTRAINDICATIONS

Known systemic hypersensitivity reactions to egg proteins (egg or egg products), to chicken proteins, or any component of VAXIGRIP® or a life-threatening reaction after previous administration of influenza vaccine or a vaccine containing the same substances. (See DOSAGE FORMS, COMPOSITION AND PACKAGING - Composition.)

Vaccination must be postponed in case of febrile or acute disease.

Immunization should be delayed in a patient with an active neurologic disorder, but should be considered when the disease process has been stabilized.

WARNINGS AND PRECAUTIONS

General

As with all products, Epinephrine Hydrochloride solution (1:1,000) and other appropriate agents should be available for immediate use in case an anaphylactic or acute hypersensitivity reaction

occurs. (3) Health-care providers should be familiar with current recommendations for the initial management of anaphylaxis in non-hospital settings including proper airway management. For instructions on recognition and treatment of anaphylactic reactions see the current edition of the Canadian Immunization Guide or visit the Health Canada website.

As each dose may contain traces of formaldehyde, Triton® X-100 and undetectable traces of neomycin, which are used during vaccine production, caution should be exercised when the vaccine is administered to subjects with hypersensitivity to one of these substances or the antibiotic and the antibiotics of the same class. (See CONTRAINDICATIONS and ADVERSE REACTIONS.) (5) The multidose vial of this vaccine contains thimerosal as a preservative. Thimerosal has been associated with allergic reactions. (6)

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

Influenza virus is remarkably unpredictable in that significant antigenic changes may occur from time to time. It is known that VAXIGRIP® 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. (3)

Administer the vaccine intramuscularly. VAXIGRIP® should not be administered into the buttocks due to the varying amount of fatty tissue in this region.

Do not administer by intravascular injection: ensure that the needle does not penetrate a blood vessel.

Use a separate, sterile needle and syringe or a sterile disposable unit for each individual patient to prevent disease transmission. There have been case reports of transmission of HIV and hepatitis by failure to scrupulously observe sterile technique. In particular, the same needle and/or syringe must never be used to re-enter a multidose vial to withdraw vaccine even when it is to be used for inoculation of the same patient. This may lead to contamination of the vial contents and infection of patients who subsequently receive vaccine from the vial. (7)

Before administration, take all appropriate precautions to prevent adverse reactions. This includes a review of the patient's history concerning possible hypersensitivity to the vaccine or similar vaccine, previous immunization history, the presence of any contraindications to immunization and current health status.

Before administration of VAXIGRIP®, health-care providers should inform the patient, parent or guardian of the benefits and risks of immunization, inquire about the recent health status of the patient and comply with any local requirements regarding information to be provided to the patient before immunization.

Hematologic

As with all injectable vaccines, VAXIGRIP® must be administered with caution to subjects with thrombocytopenia or other bleeding disorders since injection-site bleeding may occur following an intramuscular injection. (3)

Immune

If the vaccine is used in persons deficient in producing antibodies, whether due to genetic defect, immunodeficiency disease, or immunosuppressive therapy, the expected immune response may not be obtained. (3)

Respiratory

According to NACI, persons who have experienced oculo-respiratory syndrome (ORS) symptoms may be safely reimmunized with influenza vaccine. (3) Please refer to the most current NACI recommendations regarding revaccination of subjects who experienced more severe oculo-respiratory syndrome. (3)

Special Populations

Pregnant Women

Animal reproduction studies have not been conducted with VAXIGRIP®. It is not known whether VAXIGRIP® can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity.

Data on the use of this vaccine in pregnant women are limited. VAXIGRIP® should be given to pregnant women only if clearly needed and following an assessment of the risks and benefits. (See INDICATIONS AND CLINICAL USE.)

NACI states that influenza vaccination is recommended for all pregnant women. (3)

Nursing Women

It is not known whether VAXIGRIP® is excreted in human milk. Caution must be exercised when VAXIGRIP® is administered to a nursing mother.

NACI states that influenza vaccination is recommended for breastfeeding women who are characterized by any of the risk conditions in particular those who have chronic health conditions or who are close contacts of high-risk persons. (3) (See INDICATIONS AND CLINICAL USE.)

ACIP states that influenza vaccine is safe for mothers who are breastfeeding and their infants. Breastfeeding does not adversely affect the immune response and is not a contraindication for vaccination. (2) (3)

Pediatrics

The use of VAXIGRIP® in infants under 6 months of age is not recommended.

ADVERSE REACTIONS

Adverse Drug Reaction Overview

Adverse event information is derived from uncontrolled clinical trials and worldwide post-marketing experience.

Because VAXIGRIP® contains only non-infectious viruses, it cannot cause influenza. Respiratory disease after vaccination represents coincidental illness unrelated to influenza vaccination.

The most frequent side effect of influenza vaccination is soreness at the vaccination site. These local reactions generally are mild and rarely interfere with the person's ability to conduct usual daily activities. (2) Local redness, swelling, induration and bruising have also been reported. (8)

Fever, malaise, myalgia, arthralgia, lymphadenopathy, headache, shivering, sweating, fatigue (8) and other systemic symptoms can occur following vaccination with inactivated influenza vaccine and most often affect persons who have had no exposure to the influenza virus antigens in the vaccine (e.g., young children). (2) (9) These reactions usually disappear within 1-2 days without treatment.

Placebo-controlled trials suggest that among elderly persons and healthy young adults administration of split-virus influenza vaccine is not associated with higher rates of systemic symptoms (e.g., fever, malaise, myalgia and headache) when compared with placebo injections. (2) (10)

Prophylactic acetaminophen may decrease the frequency of some side effects in adults. (3) (11)

Clinical Trial Adverse Drug Reactions

Because clinical trials are conducted under very specific conditions, the adverse reaction rates observed in the clinical trials may not reflect the rates observed in practice and should not be compared to the rates in the clinical trials of another drug. Adverse drug reaction information from clinical trials is useful for identifying drug-related adverse events and for approximating rates.

The strain composition of the influenza virus vaccines is subject to annual changes and respective clinical studies, including at least 50 adults 18-60 years of age and at least 50 elderly aged 60 years or older, are conducted as annual update requirements in Europe to assess the safety and immunogenicity of VAXIGRIP®. (12)

Five years of annual clinical safety data analysis were considered. (See Table 1.) (13) (14) (15) (16) (17)

A total of 779 vaccinees received an intramuscular injection of VAXIGRIP®. The most common reactions occurring after vaccine administration were local reactions at the injection site; mainly pain and erythema, asthenia and headache. Most of the adverse events were of mild to moderate intensity, usually occurring within one day of vaccination and resolving within 3 days.

Table 1 summarizes the frequencies (range across individual trials) of the solicited adverse events that were recorded within 3 days following the vaccination.

Data are categorized by age group and by MedDRA system organ class. An asterisk indicates that the adverse event was not reported in all studies.

Table 1: Adverse Events within 3 Days after Vaccination of 779 Patients with VAXIGRIP®

Adverse Event	Adult 18-59 years (N = 393)	Elderly >60 years (N = 386)
General Disorders and Administration Site Conditions Local Reactions		
Injection site pain	27 to 57%	11.5 to 23.7%
Injection site erythema	7.1 to 29.1%	7.1 to 29.9%
Injection site induration	4.5 to 17.3%	3.8 to 10.5%
Injection site edema	2.2 to 21.5%	5.8 to 14.5%*
Injection site bruising	1.1 to 7.4%*	1.9 to 4.5%*
Injection site pruritus	1.1 to 4.9%*	1.9 to 3%*
Systemic Complaints		
Asthenia	4.3 to 14.8%	1.4 to 7.9%
Pyrexia (oral temperature >38°C)	1.2 to 1.4%*	1 to 1.5%*
Rigors	1.4 to 6.7%	1 to 3%*
Malaise	1.1 to 1.3%*	1.3%*
Nervous System Disorders		
Headache	1.4 to 10%	2.9 to 6%*
Musculoskeletal and Connective Tissue Disorders		
Arthralgia	1.4 to 3.8%*	1.5 to 2.6%*
Myalgia	1.1 to 8.9%	1.4 to 3%*
Skin and Subcutaneous Tissue Disorders		
Sweating increased	1.4 to 4.9%*	6%*

* adverse event not reported in all studies

Post-market Adverse Drug Reactions

Based on spontaneous reporting, the following additional adverse events have been reported during the commercial use of VAXIGRIP®. These events have been very rarely reported, however, exact incidence cannot precisely be calculated. (18)

- **Blood and Lymphatic System Disorders**
  Transient thrombocytopenia, lymphadenopathy.
- **Immune System Disorders**
  Allergic reactions: pruritus, rash erythematous, urticaria, dyspnea, angioneurotic edema or shock.
- **Nervous System Disorders**
  Paraesthesia, Guillain-Barré syndrome (GBS), neuritis, neuralgia, convulsions, encephalomyelitis. (8) (19) (20)
- **Vascular Disorders**
  Vasculitis, (3) such as Henoch-Schonlein purpura, with transient renal involvement in certain cases. (21) (22)

Additional Adverse Reactions

The following adverse events not listed above have been reported with influenza vaccines.

During the 2000-2001 influenza season, the Public Health Agency of Canada (PHAC) received an increased number of reports of influenza vaccine-associated symptoms and signs that were subsequently described as oculo-respiratory syndrome (ORS). The pathophysiologic mechanism underlying ORS remains unknown, but it is considered distinct from IgE-mediated allergy. (3) Since the 2000-2001 influenza season fewer ORS cases have been reported to PHAC. Approximately 5% to 34% of patients who have previously experienced ORS may have a recurrence attributable to the vaccine, but these episodes are usually milder than the original one, and persons who have a recurrence of ORS upon re-vaccination do not necessarily experience further episodes with future vaccinations. Data on clinically significant adverse events do not support the preference of one vaccine product over another when re-vaccinating those who have previously experienced ORS. (3)

Immediate – presumably allergic – reactions (e.g., hives, angioedema, allergic asthma, anaphylaxis, pruritus, erythematous rash, dyspnea) (2) (8) rarely occur after influenza vaccination. (2) These reactions probably result from hypersensitivity to certain vaccine components; the majority of reactions probably are caused by residual egg protein. (2) (See CONTRAINDICATIONS.) Although current influenza vaccines contain only a limited quantity of egg protein, this protein can induce immediate hypersensitivity reactions among persons who have severe egg allergy. Persons who have had hives, or swelling of the lips or tongue, or have experienced acute respiratory distress or collapse after eating eggs should consult a physician for appropriate evaluation to help determine if vaccine should be administered. Persons who have documented immunoglobulin E (IgE)-mediated hypersensitivity to eggs - including those who have had occupational asthma or other allergic responses to egg protein - might also be at increased risk for allergic reactions to influenza vaccine and consultation with a physician such as an allergist should be considered. (2) Persons with a history of systemic hypersensitivity (e.g., anaphylaxis) to eggs should not receive influenza vaccine.

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 (US) Institute of Medicine concluded that the evidence is inadequate to accept or reject a causal relation between GBS in adults and influenza vaccines administered since 1976. (23)

Even if GBS were a true side effect of vaccination in the years after 1976, the estimated risk for GBS of approximately 1 additional case/1 million persons vaccinated is substantially less than the risk for severe influenza, which can be prevented by vaccination among all age groups, especially persons aged ≥65 years and those who have medical indications for influenza vaccination. (2) Whether influenza vaccination specifically might increase the risk for recurrence of GBS is unknown; therefore, NACI and the US Advisory Committee on Immunization Practices (ACIP) state it is prudent to avoid vaccinating persons who are not at high risk for severe influenza complications and who are known to have experienced GBS within 6 to 8 weeks after a previous influenza vaccination. (2) (3)

Neurological disorders temporally associated with influenza vaccination such as encephalopathy (with or without permanent neurological - motor and/or sensory - deficit and/or intellectual

impairment), optic neuritis, facial paralysis, labyrinthitis, brachial plexus neuropathy, paresthesia and convulsion have been reported. However, no cause-and-effect relationships have been established. (19) Encephalomyelitis (20) and neuritis have also been reported. (8)

Physicians, nurses and pharmacists should report any adverse occurrences temporally related to the administration of the product in accordance with local requirements and to the Global Pharmacovigilance Department, Sanofi Pasteur Limited, 1755 Steeles Avenue West, Toronto, ON, M2R 3T4, Canada. 1-888-621-1146 (phone) or 416-667-2435 (fax).

DRUG INTERACTIONS

Although influenza vaccination can inhibit the hepatic clearance of warfarin, theophylline and phenytoin, (24) clinical studies have not shown any adverse effects attributable to this phenomenon in persons receiving influenza vaccine. (3)

If the vaccine is used in persons deficient in producing antibodies due to immunosuppressive therapy, the expected immune response may not be obtained.

Simultaneous Administration of Other Vaccines

Adult target groups for influenza and pneumococcal polysaccharide vaccination overlap considerably. Health-care providers should take the opportunity to immunize eligible persons against pneumococcal disease when influenza vaccine is given. Pneumococcal vaccine, in contrast to influenza vaccine is not given annually. (3) Clinical studies show that influenza vaccine may be administered with pneumococcal vaccine using separate syringes at different sites. (25) (26)

No studies regarding the simultaneous administration of inactivated influenza vaccine and other childhood vaccines have been conducted. According to NACI, inactivated vaccines usually do not interfere with the immune response to other inactivated or live vaccines (3) and influenza vaccine may be given at the same time as other vaccines, provided different sites and administration sets (needle and syringe) are used. (3)

VAXIGRIP® must not be mixed in the same syringe with other parenterals.

DOSAGE AND ADMINISTRATION

Recommended Dose

The recommended dosage schedule is presented in Table 2.

Table 2: Recommended Influenza Vaccine Dosage, by Age

Age Group	Dose	No. of Doses
6 to 35 months	0.25 mL	1 or 2*
3 to 8 years	0.5 mL	1 or 2*
≥9 years	0.5 mL	1

* Previously unvaccinated children <9 years of age require 2 doses of influenza vaccine with an interval of 4 weeks. The second dose is not needed if the child received one or more doses of vaccine during a previous influenza season. (3)

Inspect for extraneous particulate matter and/or discolouration before use. If these conditions exist, the product should not be administered.

For information on vaccine administration, see the current edition of the Canadian Immunization Guide or visit the Health Canada website.

Administer the vaccine **intramuscularly**. The preferred site is into the deltoid muscle, in adults and children >1 year of age. The preferred site for infants and young children (<1 year of age) is the anterolateral aspect of the mid-thigh (vastus lateralis muscle).

VAXIGRIP® is supplied in packages containing either: one pre-filled single dose (0.5 mL) syringe with a fixed needle, one pre-filled single-dose (0.25 mL) syringe with a fixed needle, a pre-filled single-dose
(0.5 mL) syringe co-packaged with two needles, a multidose vial, or a single-dose ampoule.

SHAKE THE PRE-FILLED SYRINGE WELL to uniformly distribute the suspension before administration.

If using a pre-filled syringe with two needles, select a needle of appropriate length to ensure that the vaccine will be delivered intramuscularly. Remove the tip cap from the syringe, take the chosen needle from the blister pack and fix to the tip of the pre-filled syringe.

For children, when a single dose 0.5 mL syringe is to be used for administration of a 0.25 mL dose, push the plunger exactly to the edge of the mark so that half of the volume is eliminated. The remaining volume should be injected.

If using a multidose vial, SHAKE THE VIAL WELL to uniformly distribute the suspension before withdrawing each dose. When administering a dose from a stoppered vial, do not remove either the stopper or the metal seal holding it in place. Aseptic technique must be used for withdrawal of each dose. (See WARNINGS AND PRECAUTIONS.)

If using an ampoule, SHAKE THE AMPOULE WELL to uniformly distribute the suspension before withdrawing each dose. Before withdrawing a dose from an ampoule, tap the container

first to ensure that any vaccine in the ampoule neck falls to the lower portion of the ampoule. Once the ampoule has been opened, any of its contents not used immediately should be discarded. Aseptic technique must be used for withdrawal of each dose. (See WARNINGS AND PRECAUTIONS.)

Do not inject intravenously.

Needles should not be recapped and should be disposed of according to biohazard waste guidelines.

Give the patient 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. This permanent office record should contain the name of the vaccine, date given, dose, manufacturer and lot number.

OVERDOSAGE

Not applicable.

ACTION AND CLINICAL PHARMACOLOGY

Mechanism of Action

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.

Immunity to the surface antigens, especially to the hemagglutinin, reduces the likelihood of infection and lessens the severity of disease if infection occurs. Antibody against one influenza virus type or subtype confers limited or no protection against another. Furthermore, antibody to one antigenic variant of influenza virus might not protect against a new antigenic variant of the same type or subtype. Frequent development of antigenic variants through antigenic drift is the virologic basis for seasonal epidemics and the reason for the usual incorporation of one or more new strains in each year’s influenza vaccine. (2)

Each year's influenza vaccine contains three virus strains (usually two type A, and one type B) representing the influenza viruses that are believed likely to circulate in the coming winter. (1) (3) The antigenic characteristics of current and emerging influenza virus strains provide the basis for selecting the strains included in each year’s vaccine. (1) (3)

Pharmacodynamics

Seroprotection is generally obtained within 2 to 3 weeks.

Pharmacokinetics

No pharmacokinetic studies have been performed.

Duration of Effect

The duration of post-vaccinal immunity varies and is usually 6-12 months. (27)

STORAGE AND STABILITY

Store at 2° to 8°C (35° to 46°F). **Do not freeze**. Discard product if exposed to freezing.

Protect from light. Do not use vaccine after expiration date.

SPECIAL HANDLING INSTRUCTIONS

A multidose vial of VAXIGRIP® which has been entered and in use for 7 days should be discarded.

DOSAGE FORMS, COMPOSITION AND PACKAGING

Dosage Forms

Vial	1 x 5 mL (Multidose)
Pre-filled Syringe	1 x 0.25 mL (Single Dose) with an attached (25G, 16 mm) needle
Pre-filled Syringe	1 x 0.5 mL (Single Dose) with an attached (25G, 16 mm) needle
Pre-filled Syringe	1 x 0.5 mL (Single Dose) co-packaged with two 25G needles of different lengths (16 mm and 25 mm)
Ampoule	1 x 0.5 mL (Single Dose)
Ampoule	5 x 0.5 mL (Single Dose)

The vial stopper, plunger stopper and the needle shield of the pre-filled syringe do not contain latex (natural rubber).

Composition

For the 2009-2010 season, each 0.5 mL dose of VAXIGRIP® contains:

15 µg HA	A/Brisbane/59/2007 (H1N1)-like strain [A/Brisbane/59/2007 (IVR-148)]
15 µg HA	A/Brisbane/10/2007 (H3N2)-like strain [A/Uruguay/716/2007 (NYMC X-175C)]
15 µg HA	B/Brisbane/60/2008-like strain (B/Brisbane/60/2008)

Other Ingredients

≤30 µg formaldehyde, up to 0.5 mL sodium phosphate-buffered, isotonic sodium chloride solution. 2 µg thimerosal*, Triton® X-100, trace amounts of sucrose and neomycin.

* added as a preservative in multidose presentation only

For the 2009-2010 season, each 0.25 mL dose of VAXIGRIP® contains:

7.5 µg HA A/Brisbane/59/2007 (H1N1)-like strain [A/Brisbane/59/2007 (IVR-148)]

7.5 µg HA A/Brisbane/10/2007 (H3N2)-like strain [A/Uruguay/716/2007 (NYMC X-175C)]

7.5 µg HA B/Brisbane/60/2008-like strain (B/Brisbane/60/2008)

Other Ingredients
≤15 µg formaldehyde, up to 0.25 mL sodium phosphate-buffered, isotonic sodium chloride solution, 1 µg thimerosal*, Triton® X-100, trace amounts of sucrose and neomycin.

* added as a preservative in multidose presentation only

After shaking, VAXIGRIP® is slightly whitish and opalescent in colour.

Vaccine Information Service: 1-888-621-1146 or 416-667-2779
Business hours: 8 a.m. to 5 p.m. Eastern Time, Monday to Friday.
Full product monograph available on request or visit us at www.sanofipasteur.ca

Product information as of April 2009.

Manufactured by:
Sanofi Pasteur SA
Lyon, France

Distributed by:
Sanofi Pasteur Limited
Toronto, Ontario, Canada

R14-0409 Canada

PART II: SCIENTIFIC INFORMATION

PHARMACEUTICAL INFORMATION

Drug Substance

VAXIGRIP® [Inactivated Influenza Vaccine Trivalent Types A and B (Split Virion)]

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7.5 µg HA B/Brisbane/60/2008-like strain (B/Brisbane/60/2008).

Other Ingredients

≤15 µg formaldehyde, up to 0.25 mL sodium phosphate-buffered, isotonic sodium chloride solution, 1 µg thimerosal*, Triton® X-100, trace amounts of sucrose and neomycin.

* added as a preservative in multidose presentation only

The type and amount of viral antigens contained in VAXIGRIP® conform to the current requirements of the World Health Organization (WHO). (1)

Product Characteristics

VAXIGRIP® for intramuscular use is a sterile suspension prepared from influenza viruses cultivated in embryo-containing hens' eggs. Each of the strains is separately inoculated into the allantoic cavity of chicken embryos aged 11 days with neomycin solution equivalent to 0.5 mg per egg. Following incubation, the allantoic fluid is collected and clarified, the viruses are concentrated, and then purified by zonal centrifugation using a sucrose density gradient. Subsequent stages consist of treatment with Triton® X-100 to obtain split antigens, then inactivation using formaldehyde solution. The final vaccine is obtained by mixing the three strains in a buffer. Thimerosal is then added for the multidose presentation only.

After shaking, VAXIGRIP® is slightly whitish and opalescent in colour.

CLINICAL TRIALS

Study Demographics and Trial Design

The immunogenicity of VAXIGRIP® has been demonstrated in clinical trials in adults (age 18-60 years), elderly (age >60 years), and young children (age 6-36 months and 3-10 years). The strain composition of influenza virus vaccines is subject to annual changes, and annual studies in adults to verify the immunogenicity are performed. (See Table 3.) In the annual studies (8) and in study 3 (28), a single dose of VAXIGRIP® was given and antibody titres were assessed immediately before vaccination and 21 days later. In study 2, (29) antibody titres were assessed immediately before the first dose and 27-33 days following the second vaccine dose.

Table 3: Summary of Patient Demographics for Clinical Trials

Study #	Trial design	Dosage, route of administration and duration	Study subjects (n=number)	Mean age (Range)	Gender
Annual Study (8)	Open	0.5 mL IM	n >50 n >50	18-60 years >60 years	--
Study 2 (8) (29)	Open	0.25 mL IM; 2 doses 1 month apart	n = 65	6 months to 3 years	Male 37 Female 28
Study 3 (28)	Open	0.5 mL	n = 42 (12 had received prior influenza vaccination)	8-10 years	Male 19 Female 23

Study Results

The efficacy of influenza vaccine is assessed using a surrogate for protection defined as the immune response elicited by the vaccine (hemagglutination inhibition). In the annual studies, the serologic responses of both adult age groups to all antigens must meet the assessment criteria as defined in the European Requirements for Influenza Vaccines (i.e., for subjects 18-60 years – at least one of seroconversion or significant increase in antihemagglutinin antibody titre in >40%, mean GMT increase >2.5, proportion of subjects achieving HI (hemagglutination inhibition) titre or seroprotection >70%, and for subjects >60 years at least one of seroconversion or significant increase in antihemagglutinin antibody titre in >30%, mean GMT increase >2.0, proportion of subjects achieving HI titre >60%.) (12) Elderly subjects generally respond less well to influenza vaccines than young healthy adults, and those with chronic debilitating medical conditions generally respond less well than healthy subjects of similar age. (30)

The results in children met the criteria defined for young adults; no criteria for children have been set.

DETAILED PHARMACOLOGY

Influenza A and B are the two types of influenza viruses that cause epidemic human disease. Influenza A viruses are further categorized into subtypes on the basis of two surface antigens: hemagglutinin (H) and neuraminidase (N). Influenza B viruses are not categorized into subtypes. (3) Since 1977, influenza A (H1N1) viruses, influenza A (H3N2) viruses and influenza B viruses have been in global circulation. (3) Influenza A (H1N2) has been circulating widely since 2001. (3) Because circulating influenza A (H1N2) viruses are a reassortant of influenza A (H1N1) and

(H3N2) viruses, antibody directed against influenza A (H1N1) and (H3N2) vaccine strains will provide protection against circulating influenza A (H1N2) viruses. (3)

In the tropics, influenza can occur throughout the year. In the southern hemisphere, peak activity occurs from April through September.

Uncomplicated influenza illness is characterized by the abrupt onset of constitutional and respiratory signs and symptoms (e.g., fever, myalgia, headache, malaise, non-productive cough, sore throat and rhinitis). Illness typically resolves after a limited number of days for the majority of persons, although cough and malaise can persist for two or more weeks. Among certain persons, influenza can exacerbate underlying medical conditions (e.g., pulmonary or cardiac disease), lead to secondary bacterial pneumonia or primary influenza viral pneumonia, or occur as part of a coinfection with other viral or bacterial pathogens. (3) The spectrum of influenza in children ranges from asymptomatic infection to influenza illness with or without complications. In addition to febrile upper respiratory tract infection, common clinical presentations of influenza in children include lower respiratory tract infection (croup, bronchiolitis, primary viral, or secondary bacterial pneumonia), otitis media, diarrheal illness, and febrile seizures. Influenza infection has also been associated with encephalopathy, transverse myelitis, Reye syndrome, myositis, myocarditis, and pericarditis. (3) The risks of complications, hospitalizations and deaths from influenza are higher among persons 65 years of age or older, young children and persons of any age with some underlying health conditions than among healthy older children and younger adults. (3)

Vaccination is recognized as the single most effective way of preventing or attenuating influenza for those at high risk of serious illness or death from influenza infection and related complications. (3)

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.

Immunity to the surface antigens, especially to the hemagglutinin, reduces the likelihood of infection and severity of disease if infection occurs. Antibody against one influenza virus type or subtype confers limited or no protection against another. Furthermore, antibody to one antigenic variant of influenza virus might not protect against a new antigenic variant of the same type or subtype. Frequent development of antigenic variants through antigenic drift is the virologic basis for seasonal epidemics and the reason for the usual incorporation of one or more new strains in each year's influenza vaccine. (2)
Each year's influenza vaccine contains three virus strains (usually two type A and one type B) representing the influenza viruses that are believed likely to circulate in the coming winter. (1) (3) The antigenic characteristics of current and emerging influenza virus strains provide the basis for selecting the strains included in each year's vaccine. (1) (3) The WHO reviews the world epidemiological situation annually and if necessary recommends new strains based on the current epidemiological evidence.

The majority of vaccinated children and young adults develop high post-vaccination hemagglutination inhibition antibody titres. These antibody titres are protective against illness caused by strains similar to those in the vaccine. Older persons and persons with certain chronic diseases might develop lower post-vaccination antibody titres than healthy young adults and thus can remain susceptible to influenza-related upper respiratory tract infection. The vaccine can also

be effective in preventing secondary complications and reducing the risk for influenza-related hospitalization and death among adults 65 years and older with and without high-risk medical conditions (e.g., heart disease and diabetes). (2)

The effectiveness of influenza vaccine varies depending upon the age and immunocompetence of the vaccine recipient, the degree of similarity between the virus strain included and the characteristics of the strain of circulating virus during the influenza season. With a good match, influenza vaccination has been shown to prevent laboratory-confirmed influenza illness in approximately 70% or more of healthy individuals. (31) In the elderly, vaccination against influenza is associated with reductions in the risk of hospitalization for heart disease, cerebrovascular disease, and pneumonia or influenza as well as the risk of death from all causes during influenza season. (32) In older persons living in residential facilities influenza vaccine prevents pneumonia, hospital admission, death from pneumonia (vaccine effectiveness 42% to 46%), and all-cause mortality (vaccine effectiveness 60%). (32)

Children aged as young as 6 months can develop protective levels of antibody after influenza vaccination, although the antibody response among children at high risk of influenza-related complications might be lower than among healthy children. In a randomized study among children aged 1 - 15 years, inactivated influenza vaccine was 77% - 91% effective against influenza respiratory illness. (2) Vaccination of health-care workers has been associated with reduced work absenteeism (2) (33) and decreased deaths among nursing home patients. (2) (34)

Vaccination is associated with reductions in influenza-related respiratory illness and physician visits among all age groups, hospitalization and death among persons at high risk, otitis media among children and work absenteeism among adults. (2) (35)

Although the current influenza vaccine can contain one or more of the antigens administered in previous years, annual vaccination using the current vaccine is necessary because immunity declines in the year following vaccination.

TOXICOLOGY

Data in animals revealed no unexpected findings and no target organ toxicity. (36) (37) (38)

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Vaccine Information Service: 1-888-621-1146 or 416-667-2779.
Business hours: 8 a.m. to 5 p.m. Eastern Time, Monday to Friday.
Full product monograph available on request or visit us at www.sanofipasteur.ca

Product information as of April 2009.

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Sanofi Pasteur SA
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Distributed by:
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Toronto, Ontario, Canada

R14-0409 Canada

IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

VAXIGRIP®

Inactivated Influenza Vaccine Trivalent Types A and B (Split Virion)

This leaflet is part III of a three-part "Product Monograph" published when VAXIGRIP® was approved for sale in Canada. It provides important information about the product for Consumers. This leaflet is a summary and it does not tell you everything about VAXIGRIP®. Contact your doctor, nurse or pharmacist if you have any questions about the vaccine.

ABOUT THIS MEDICATION

VAXIGRIP® is a vaccine used to prevent influenza. Influenza (or flu) is an infection caused by the influenza virus.

This vaccine may be given to adults and children 6 months of age and older.

Flu symptoms can include fever, headache, muscle pain, runny nose, sore throat, extreme tiredness and cough. Some people get much sicker.

The influenza virus spreads when a person who has the flu coughs or sneezes into the air. Small droplets of the flu virus stay in the air for a short time then fall onto surfaces nearby. You can get the flu by:
- breathing in these droplets through your nose or mouth.
- the droplets landing directly on your eyes.
- touching the hands of a person who has the flu and then touching your eyes, nose or mouth.
- touching surfaces that have been contaminated with flu virus and then touching your eyes, nose or mouth.

What it does:

VAXIGRIP® causes your body to produce its own protection against influenza virus. After you get a flu shot, your immune system produces antibodies against the strains of virus that are in the vaccine. The antibodies are effective for six to 12 months. When you are exposed to the virus, the antibodies will help to keep you from getting sick. If you do get the flu, you may not be as sick.

When it should not be used:

VAXIGRIP® should not be used in the following situations:

Do not give VAXIGRIP® to anyone who has ever had an allergic reaction to:

- egg or egg products
- chicken protein
- any component of VAXIGRIP® or its container.

Do not give VAXIGRIP® to a person who has a fever or serious illness. Wait until the person is better before giving the flu shot. A person who has a mild illness (such as a mild cold) may have the flu shot. Ask your doctor, nurse or pharmacist for advice.

What the medicinal ingredient is:

Each 0.5 mL dose of VAXIGRIP® contains killed split viruses from three strains of influenza virus for the 2009-2010 season. The viruses in VAXIGRIP® are:

A/Brisbane/59/2007 (H1N1)-like strain [A/Brisbane/59/2007 (IVR-148)], A/Brisbane/10/2007 (H3N2)-like strain [A/Uruguay/716/2007 (NYMC X-175C)] and B/Brisbane/60/2008-like strain (B/Brisbane/60/2008).

What the important nonmedicinal ingredients are:

Thimerosal (only in the multidose vial), neomycin, formaldehyde, sodium phosphate-buffered, isotonic sodium chloride solution, Triton® X-100 and sucrose.

What dosage forms it comes in:

Individual doses in a prefilled syringe (needle) or a vial that contains enough vaccine for many doses.

WARNINGS AND PRECAUTIONS

VAXIGRIP® will only protect against the strains of flu virus contained in the vaccine or those that are closely related.
VAXIGRIP® will not protect against any other strains of flu virus.

If you have any of the following conditions, talk to your doctor, nurse or pharmacist BEFORE you use VAXIGRIP®:

- **Persons who have diseases of the immune system or who are having treatment that affects the immune system.** The vaccine may provide you with a lower level of protection than it does for people with healthy immune systems.
- **Persons who have coagulation disorders or are on anticoagulant therapy.** Tell the person giving you the injection about your condition. There is a risk of excessive bleeding where you get the injection if it is not done carefully.
- **Pregnant or breast-feeding women.** It is important that you understand the risks and benefits of vaccination. VAXIGRIP® should be given to a pregnant or nursing woman only if it is clearly needed. Tell the person giving you the injection if you are pregnant or breast-feeding.

- **Persons with an allergy to any component of the vaccine or the container.**

The use of VAXIGRIP® in infants under 6 months of age is not recommended.

As with all vaccines, VAXIGRIP® does not protect 100% of people immunized.

INTERACTIONS WITH THIS MEDICATION

VAXIGRIP® must not be mixed with other vaccines or medicinal products in the same syringe.

PROPER USE OF THIS MEDICATION

Usual dose:

For children 6 to 35 months - recommended dose is 0.25 mL.

For persons 3 years or older - recommended dose is 0.5 mL.

Children under 9 years of age who have not received a previous vaccination - 2 doses are required 4 weeks apart. The second dose is not needed if the child received one or more doses of influenza vaccine during a previous season.

For adults and children older than 1 year, inject the vaccine into the deltoid (shoulder) muscle.

For infants and children less than 1 year inject the vaccine into the mid-thigh muscle.

Overdose: Not applicable to this vaccine.

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

A vaccine, like any medicine, may cause serious problems, such as severe allergic reactions. The risk of VAXIGRIP® causing serious harm is extremely small. The small risks associated with VAXIGRIP® are much less than the risks associated with getting the disease against which it protects.

The flu vaccine cannot cause influenza because it does not contain any live virus. The most common side effect is soreness where you got the injection. It may last a couple of days. You might also notice fever, fatigue and muscle aches within 6 to 12 hours after your shot. These side effects may last a day or two.

Severe allergic reactions to the flu shots are very rare. A very rare but possible side effect of influenza vaccination is Guillain-Barré syndrome (GBS). This is an autoimmune disease that attacks the nervous system. GBS causes weakness and abnormal sensations. Most patients recover fully. Your chance of developing GBS as a result of a flu shot is one in a million.

This is not a complete list of side effects. Talk to your doctor or nurse before receiving VAXIGRIP®.

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well after having VAXIGRIP®.

For any unexpected effects after having VAXIGRIP®, contact your doctor, nurse or pharmacist.

HOW TO STORE IT

Store in a refrigerator at 2° to 8°C (35° to 46°F). DO NOT FREEZE. Protect from light. Discard product if it has been exposed to freezing.

Do not use vaccine after expiration date.

Discard open multidose vials of VAXIGRIP® after 7 days.

Keep VAXIGRIP® out of children's reach.

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 telephone: 613-954-5590
by toll-free telephone: 1-866-844-0018
by fax: 613-954-9874
by toll-free fax: 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, A/L 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 monograph, prepared for health professionals can be found at: http://www.sanofipasteur.ca or by contacting the vaccine producer, Sanofi Pasteur Limited, 1755 Steeles Avenue West, Toronto, Ontario, M2R 3T4.

Phone: 1-888-621-1146 or 416-667-2779.

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