FLUARIX 2025/2026- influenza virus vaccine suspension
GlaxoSmithKline Biologicals SA

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use FLUARIX safely and effectively. See full prescribing information for FLUARIX.

FLUARIX (Influenza Vaccine)
Injectable Suspension, for Intramuscular Use
2025-2026 Formula
Initial U.S. Approval: 2005

INDICATIONS AND USAGE

FLUARIX is a vaccine indicated for active immunization for the prevention of disease caused by influenza A subtype viruses and type B virus contained in the vaccine. FLUARIX is approved for use in persons aged 6 months and older. (1)

DOSAGE AND ADMINISTRATION

For intramuscular use. (2)

Age	Vaccination Status	Dose and Schedule
6 months through 8 years	Not previously vaccinated with influenza vaccine	Two doses (0.5 mL each) at least 4 weeks apart (2.1)
	Vaccinated with influenza vaccine in a previous season	One or 2 doses[a] (0.5 mL each) (2.1)
9 years and older	Not applicable	One 0.5-mL dose (2.1)

[a] One dose or 2 doses (0.5 mL each) depending on vaccination history as per the annual Advisory Committee on Immunization Practices (ACIP) recommendation on prevention and control of seasonal influenza with vaccines. If 2 doses, administer each 0.5-mL dose at least 4 weeks apart. (2.1)

DOSAGE FORMS AND STRENGTHS

FLUARIX is an injectable suspension. A single dose is 0.5 mL. (3)

CONTRAINDICATIONS

Do not administer FLUARIX to anyone with a history of severe allergic reactions (e.g., anaphylaxis) to any component of the vaccine, including egg protein, or following a previous dose of any influenza vaccine. (4, 11)

WARNINGS AND PRECAUTIONS

- If Guillain-Barré syndrome has occurred within 6 weeks of receipt of a prior influenza vaccine, the decision to give FLUARIX should be based on careful consideration of potential benefits and risks. (5.1)
- Syncope (fainting) can occur in association with administration of injectable vaccines, including FLUARIX. Procedures should be in place to avoid injury from fainting. (5.2)

ADVERSE REACTIONS

- In adults who received FLUARIX, the most common (≥10%) solicited local adverse reactions were pain (55%) and redness (18%); the most common systemic adverse reactions were muscle aches (23%), fatigue (20%), and headache (19%). (6.1)
- In children aged 5 through 17 years who received FLUARIX, the most common (≥10%) solicited local adverse reactions were pain (56%), redness (18%), and swelling (14%); the most common systemic adverse reactions were muscle aches (29%), fatigue (20%), and headache (15%). (6.1)
- In children aged 3 through 4 years who received FLUARIX, the most common (≥10%) solicited local adverse reactions were pain (35%), redness (23%), and swelling (14%); the most common systemic adverse reactions were irritability (21%), loss of appetite (13%), and drowsiness (13%). (6.1)
- In children aged 6 through 35 months who received FLUARIX QUADRIVALENT, the most common (≥10%) solicited local adverse reactions were pain (17%) and redness (13%); the most common systemic adverse reactions were irritability (16%), loss of appetite (14%), and drowsiness (13%). (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact GlaxoSmithKline at 1-888-825-5249 or

VAERS at 1-800-822-7967 or www.vaers.hhs.gov.

USE IN SPECIFIC POPULATIONS

- Geriatric Use: Antibody responses were lower in geriatric subjects who received FLUARIX than in younger subjects. (8.5)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 7/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

FLUARIX is indicated for active immunization for the prevention of disease caused by influenza A subtype viruses and type B virus contained in the vaccine *[see Description (11)]*. FLUARIX is approved for use in persons aged 6 months and older.

2 DOSAGE AND ADMINISTRATION

For intramuscular use.

2.1 Dosage and Schedule

The dose and schedule for FLUARIX are presented in Table 1.

Table 1. FLUARIX: Dosing

Age	Vaccination Status	Dose and Schedule
6 months through 8 years	Not previously vaccinated with influenza vaccine	Two doses (0.5 mL each) at least 4 weeks apart
	Vaccinated with influenza vaccine in a previous season	One or 2 doses[a] (0.5 mL each)
9 years and older	Not applicable	One 0.5-mL dose

[a] One dose or 2 doses (0.5 mL each) depending on vaccination history as per the annual Advisory Committee on Immunization Practices (ACIP) recommendation on prevention and control of seasonal influenza with vaccines. If 2 doses, administer each 0.5-mL dose at least 4 weeks apart.

2.2 Administration Instructions

Shake well before administration. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If either of these conditions exists, the vaccine should not be administered.

Attach a sterile needle to the prefilled syringe and administer intramuscularly.

3 DOSAGE FORMS AND STRENGTHS

FLUARIX is an injectable suspension. A single dose is 0.5 mL.

4 CONTRAINDICATIONS

Do not administer FLUARIX to anyone with a history of severe allergic reactions (e.g., anaphylaxis) to any component of the vaccine, including egg protein, or following a previous administration of any influenza vaccine *[see Description (11)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Guillain-Barré Syndrome

If Guillain-Barré syndrome (GBS) has occurred within 6 weeks of receipt of a prior influenza vaccine, the decision to give FLUARIX should be based on careful consideration of the potential benefits and risks.

The 1976 swine influenza vaccine was associated with an increased frequency of GBS. Evidence for a causal relation of GBS with subsequent vaccines prepared from other influenza viruses is inconclusive. If influenza vaccine does pose a risk, it is probably slightly more than 1 additional case/1 million persons vaccinated.

5.2 Syncope

Syncope (fainting) may occur in association with administration of injectable vaccines, including FLUARIX. Procedures should be in place to avoid injury from fainting.

5.3 Preventing and Managing Allergic Vaccine Reactions

Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of FLUARIX.

5.4 Altered Immunocompetence

If FLUARIX is administered to immunosuppressed persons, including individuals receiving immunosuppressive therapy, the immune response may be lower than in immunocompetent persons.

5.5 Limitations of Vaccine Effectiveness

Vaccination with FLUARIX may not protect all susceptible individuals.

6 ADVERSE REACTIONS

The safety experience with FLUARIX QUADRIVALENT is relevant to FLUARIX because both vaccines are manufactured using the same process and have overlapping compositions.

In adults who received FLUARIX in a randomized, placebo-controlled study, the most common (≥10%) solicited local adverse reactions were pain (55%) and redness (18%). The most common systemic adverse reactions were muscle aches (23%), fatigue (20%), and headache (19%).

In children aged 5 through 17 years who received FLUARIX, the most common (≥10%) solicited local adverse reactions were pain (56%), redness (18%), and swelling (14%). The most common systemic adverse reactions were muscle aches (29%), fatigue (20%), and headache (15%).

In children aged 3 through 4 years who received FLUARIX, the most common (≥10%) solicited local adverse reactions were pain (35%), redness (23%), and swelling (14%). The most common systemic adverse reactions were irritability (21%), loss of appetite (13%), and drowsiness (13%).

In children aged 6 through 35 months who received FLUARIX QUADRIVALENT, the most common (≥10%) solicited local adverse reactions were pain (17%) and redness (13%). The most common (≥10%) systemic adverse reactions were irritability (16%), loss of appetite (14%), and drowsiness (13%).

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared with rates in the clinical trials of another vaccine and may not reflect the rates observed in practice. There is the possibility that broad use of FLUARIX could reveal adverse reactions not observed in clinical trials.

FLUARIX has been administered to 10,317 individuals aged 18 through 64 years and 606 individuals aged 65 years and older in 4 clinical trials and to 1,698 individuals aged 3 through 17 years in 1 clinical trial. FLUARIX QUADRIVALENT has been administered to 6,006 individuals aged 6 through 35 months in 1 clinical trial.

Individuals Aged 18 Years and Older

Trial 1 (NCT00100399) was a randomized, double-blind, placebo-controlled trial that evaluated a total of 952 subjects: FLUARIX (N = 760) and placebo (N = 192). The population was aged 18 through 64 years (mean: 39.1), 54% were female and 80% were white. Solicited adverse reactions were collected for 4 days (day of vaccination and the next 3 days) (Table 2). Unsolicited events that occurred within 21 days of vaccination (Day 0 to 20) were recorded using diary cards supplemented by spontaneous reports and a medical history as reported by subjects.

Table 2. FLUARIX: Incidence of Solicited Local and Systemic Adverse Reactions within 4 Days[a] of Vaccination in Adults Aged 18 through 64 Years[b] (Total Vaccinated Cohort)

	FLUARIX n = 760 %		Placebo n = 192 %	
Adverse Reaction	**Any**	**Grade 3[c]**	**Any**	**Grade 3[c]**
Local				
Pain	55	0.1	12	0
Redness	18	0	10	0
Swelling	9	0.1	6	0
Systemic				
Muscle aches	23	0.4	12	0.5
Fatigue	20	0.4	18	1
Headache	19	0.1	21	1
Arthralgia	6	0.1	6	0.5
Shivering	3	0.1	3	0
Fever[d]	2	0	2	0

Total vaccinated cohort for safety included all vaccinated subjects for whom safety data were available.
n = Number of subjects with diary card completed.

[a] Four days included day of vaccination and the subsequent 3 days.
[b] Trial 1: NCT00100399.
[c] Grade 3 pain, muscle aches, fatigue, headache, arthralgia, shivering: Defined as prevented normal activity.
Grade 3 redness, swelling: Defined as >50 mm.
Grade 3 fever: Defined as >102.2°F (39.0°C).
[d] Fever: Defined as ≥100.4°F (38.0°C).

Unsolicited adverse events that occurred in ≥1% of recipients of FLUARIX and at a rate greater than placebo included upper respiratory tract infection (3.9% versus 2.6%), nasopharyngitis (2.5% versus 1.6%), nasal congestion (2.2% versus 2.1%), diarrhea (1.6% versus 0%), influenza-like illness (1.6% versus 0.5%), vomiting (1.4% versus 0%), and dysmenorrhea (1.3% versus 1.0%).

Trial 2 (NCT00197288) was a randomized, single-blind, active-controlled U.S. trial which evaluated subjects randomized to receive FLUARIX (N = 917) or FLUZONE (N = 910), a U.S.-licensed trivalent, inactivated influenza vaccine (Sanofi Pasteur SA) stratified by age: 18 through 64 years and 65 years and older. In the overall population, 59% of subjects were female and 91% were white. Solicited adverse reactions were collected using diary cards for 4 days (day of vaccination and the next 3 days) (Table 3). Unsolicited events that occurred within 21 days of vaccination (Day 0 to 20) were recorded using diary cards.

Table 3. FLUARIX: Incidence of Solicited Local and Systemic Adverse Reactions within 4 Days[a] of Vaccination in Adults[b](Total Vaccinated Cohort)

	Aged 18 through 64 Years				Aged 65 Years and Older			
Adverse Reaction	FLUARIX n = 315 %		Comparator n = 314 %		FLUARIX n = 601-602 %		Comparator n = 596 %	
	Any	Grade 3[c]	Any	Grade 3[c]	Any	Grade 3[c]	Any	Grade 3[c]
Local								
Pain	48	0.3	53	0.3	19	0	18	0
Redness	13	0	16	1	11	0.2	13	0.7
Swelling	9	0	11	2	6	0	9	0.7
Systemic								
Fatigue	21	0.3	18	0.6	9	0.3	10	0.7
Headache	20	0.3	21	1	8	0.3	8	0.3
Muscle aches	16	0	13	1	7	0.3	7	0
Arthralgia	9	0	9	0.6	6	0.5	5	0.2
Shivering	3	0	5	0	2	0.2	2	0
Fever[d]	3	0	1	0	2	0	0.5	0

Total vaccinated cohort for safety included all vaccinated subjects for whom safety data were available.
n = Number of subjects with diary card completed.
[a] Four days included day of vaccination and the subsequent 3 days.
[b] Trial 2: NCT00197288. The active control was FLUZONE, a U.S.-licensed trivalent, inactivated influenza vaccine (Sanofi Pasteur Inc.).

inactivated influenza vaccine (Sanofi Pasteur Inc.).
[c] Grade 3 pain, muscle aches, fatigue, headache, arthralgia, shivering: Defined as prevented normal activity.
Grade 3 redness, swelling: Defined as >50 mm.
Grade 3 fever: Defined as >102.2°F (39.0°C).
[d] Fever: Defined as ≥99.5°F (37.5°C).

Unsolicited adverse events that occurred in ≥1% of all recipients of FLUARIX or the comparator influenza vaccine in the 21-day post-vaccination period included headache (2.8% versus 2.3%), back pain (1.5% versus 0.4%), pain in extremity (1.2% versus 0.7%), pharyngolaryngeal pain (1.2% versus 0.9%), cough (1.1% versus 0.9%), fatigue (1.1% versus 0.7%), nasopharyngitis (1.0% versus 1.3%), nausea (0.4% versus 1.0%), arthralgia (0.3% versus 1.0%), and injection site pruritus (0.2% versus 1.0%).

Trial 3 (NCT00363870) was a double-blind, placebo-controlled trial in subjects aged 18 through 64 years randomized (2:1) to receive FLUARIX (N = 5,103) or placebo (N = 2,549) which was conducted to evaluate the efficacy of FLUARIX. In the total population, 60% were female and 99.9% were white. In a subset (FLUARIX [N = 305] and placebo [N = 155]), unsolicited events that occurred within 21 days of vaccination (Day 0 to 20) were recorded on diary cards. The percentage of subjects reporting at least one unsolicited event was similar among the groups (24.3% for FLUARIX and 22.6% for placebo). Unsolicited adverse events that occurred in ≥1% of recipients of FLUARIX and at a rate greater than placebo included injection site pain (5.2% versus 1.3%), dysmenorrhea (1.3% versus 0.6%), and migraine (1.0% versus 0.0%).

Serious Adverse Events: In 4 clinical trials in adults (N = 10,923), there was a single case of anaphylaxis reported with FLUARIX (<0.01%).

Incidence of Adverse Events Reported in ≥1% of Subjects in Non-US Clinical Trials: The following additional adverse events have been observed in adults in 3 additional non-US clinical trials with FLUARIX. No adverse events were observed at an incidence of >10%.

General Disorders and Administration Site Conditions: Injection site ecchymosis, injection site induration, malaise.

Infections and Infestations: Rhinitis.

Musculoskeletal and Connective Tissue Disorders: Musculoskeletal pain, neck pain.

Skin and Subcutaneous Tissue Disorders: Sweating.

In a clinical trial (NCT01204671) in which 3,036 adults (18 years of age and older) received FLUARIX QUADRIVALENT, the unsolicited adverse reactions that occurred most frequently (≥ 0.1%) following administration of FLUARIX QUADRIVALENT included dizziness, injection site hematoma, injection site pruritus, and rash.

Individuals Aged 6 Months through 17 Years

Trial 4 (NCT00383123) was a single-blind, active-controlled U.S. trial which evaluated subjects aged 6 months through 17 years who received FLUARIX (N = 2,081) or FLUZONE (N = 1,173), a U.S.-licensed trivalent, inactivated influenza vaccine (Sanofi Pasteur SA). Children aged 6 months through 8 years with no history of influenza vaccination received 2 doses approximately 28 days apart. Children aged 6 months through 8 years with a history of influenza vaccination and children aged 9 years and older received 1 dose. Children aged 6 months through 35 months received 0.25 mL of

FLUARIX (not an approved dose of FLUARIX) or comparator influenza vaccine, and children aged 3 years and older received 0.5 mL of FLUARIX or comparator influenza vaccine.

Trial subjects were aged 6 months through 17 years and 49% were female; 68% were white, 18% were black, 3% were Asian, and 11% were of other racial/ethnic groups.

Solicited local and systemic adverse reactions were collected using diary cards for 4 days (day of vaccination and the next 3 days). Unsolicited adverse events that occurred within 28 days of vaccination (Day 0 to 27) after the first vaccination in all subjects and 21 days (Day 0 to 20) after the second vaccination in unprimed subjects were recorded using diary cards.

The frequencies of solicited adverse reactions for children aged 3 years through 4 years and for children aged 5 years through 17 years were similar for FLUARIX and the comparator vaccine (Table 4).

Table 4. FLUARIX: Incidence of Solicited Local and Systemic Adverse Reactions within 4 Days[a] of First Vaccination in Children Aged 3 through 17 Years[b] (Total Vaccinated Cohort)

	Aged 3 through 4 Years				Aged 5 through 17 Years			
Adverse Reaction	FLUARIX n = 350 %		Comparator n = 341 %		FLUARIX n = 1,348 %		Comparator n = 451 %	
	Any	Grade 3[c]	Any	Grade 3[c]	Any	Grade 3[c]	Any	Grade 3[c]
Local								
Pain	35	2	38	1	56	0.8	56	0.7
Redness	23	0.3	20	0	18	1	16	0.7
Swelling	14	0	13	0	14	2	13	0.7
Systemic								
Irritability	21	0.9	22	0	–	–	–	–
Loss of appetite	13	0.9	15	0.9	–	–	–	–
Drowsiness	13	0.6	20	0.9	–	–	–	–
Fever[d]	7	1	8	2	4	0.3	3	0.2
Muscle aches	–	–	–	–	29	0.4	29	0.4
Fatigue	–	–	–	–	20	1	19	1
Headache	–	–	–	–	15	0.5	16	0.9
Arthralgia	–	–	–	–	6	0.1	6	0.2
Shivering	–	–	–	–	3	0.1	4	0.2

Total vaccinated cohort for safety included all vaccinated subjects for whom safety data were available.
n = Number of subjects with diary card completed.
[a] Four days included day of vaccination and the subsequent 3 days.
[b] Trial 4: NCT00383123. The active control was FLUZONE, a U.S.-licensed trivalent, inactivated influenza vaccine (Sanofi Pasteur Inc.).
[c] Grade 3 pain, irritability, loss of appetite, drowsiness, muscle aches, fatigue, headache, arthralgia, shivering: Defined as prevented normal activity.

Grade 3 swelling, redness: Defined as >50 mm.
Grade 3 fever: Defined as >102.2°F (39.0°C).
[d] Fever: Defined as ≥99.5°F (37.5°C).

In children who received a second dose of FLUARIX or the comparator vaccine, the incidences of adverse reactions following the second dose were similar to those observed after the first dose.

Unsolicited adverse events that occurred in ≥1% of recipients of FLUARIX aged 6 months through 17 years included upper respiratory tract infection (5.5%), pyrexia (4.8%), cough (4.7%), vomiting (3.2%), headache (2.8%), rhinorrhea (2.7%), diarrhea (2.5%), pharyngolaryngeal pain (2.4%), nasopharyngitis (2.3%), otitis media (2.0%), nasal congestion (1.8%), upper abdominal pain (1.4%), and upper respiratory tract congestion (1.0%). The incidences of these events were similar in recipients of the comparator vaccine.

Trial 5 (NCT01439360) was a randomized, observer-blind, non-influenza vaccine-controlled trial evaluating the efficacy of FLUARIX QUADRIVALENT. In this trial, subjects aged 6 through 35 months received FLUARIX QUADRIVALENT (n = 6,006) or a control vaccine (n = 6,012). The comparator was pneumococcal 13-valent conjugate vaccine [Diphtheria CRM197 Protein] (Wyeth Pharmaceuticals, Inc.) in children younger than 12 months, HAVRIX (Hepatitis A Vaccine) in children 12 months and older with a history of influenza vaccination, or HAVRIX (Dose 1) and a varicella vaccine (U.S. Licensed Manufactured by Merck & Co., Inc. or Non-U.S. Licensed Manufactured by GlaxoSmithKline Biologicals) (Dose 2) in those with no history of influenza vaccination. Subjects were aged 6 through 35 months, and one child aged 43 months (mean age: 22 months); 51% were male; 27% were white, 45% were Asian, and 28% were of other racial/ethnic groups. Children aged 12 months and older with no history of influenza vaccination and children younger than 12 months received 2 doses of FLUARIX QUADRIVALENT or the control vaccine approximately 28 days apart. Children aged 12 months and older with a history of influenza vaccination received one dose. Solicited local adverse reactions and systemic adverse events were collected using diary cards for 7 days (day of vaccination and the next 6 days). The incidences of solicited adverse reactions are shown in Table 5.

Table 5. FLUARIX QUADRIVALENT: Incidence of Solicited Local and Systemic Adverse Reactions within 7 Days[a] after First Vaccination in Children Aged 6 through 35 Months[b] (Total Vaccinated Cohort)

Adverse Reactions	FLUARIX QUADRIVALENT %		Non-Influenza Active Comparator[c,d] %	
	Any	Grade 3[e]	Any	Grade 3[e]
Local	**n = 5,899**		**n = 5,896**	
Pain	17	0.4	18	0.5
Redness	13	0	14	0
Swelling	8	0	9	0
Systemic	**n = 5,898**		**n = 5,896**	
Irritability	16	0.7	18	1
Loss of appetite	14	1	15	1

Drowsiness	13	0.7	14	0.9
Fever[f]	6	1	7	1

Total vaccinated cohort for safety included all vaccinated subjects for whom safety data were available.
n = Number of subjects with diary card completed.
[a] Seven days included day of vaccination and the subsequent 6 days.
[b] Trial 5: NCT01439360.
[c] Children younger than 12 months: pneumococcal 13-valent conjugate vaccine [Diphtheria CRM_{197} Protein] (Wyeth Pharmaceuticals, Inc.).
[d] Children 12 months and older: HAVRIX (Hepatitis A Vaccine) for those with a history of influenza vaccination; or HAVRIX (Dose 1) and a varicella vaccine (U.S. Licensed Manufactured by Merck & Co., Inc. or Non-U.S. Licensed Manufactured by GlaxoSmithKline Biologicals) (Dose 2) for those with no history of influenza vaccination.
[e] Grade 3 pain: Defined as cried when limb was moved/spontaneously painful.
Grade 3 swelling, redness: Defined as >50 mm.
Grade 3 irritability: Defined as crying that could not be comforted/prevented normal activity. Grade 3 loss of appetite: Defined as not eating at all.
Grade 3 drowsiness: Defined as prevented normal activity. Grade 3 fever: Defined as >102.2°F (39.0°C).
[f] Fever: Defined as ≥100.4°F (38.0°C).

In children who received a second dose of FLUARIX QUADRIVALENT or the Non-Influenza Active Comparator vaccine, the incidences of solicited adverse reactions following the second dose were generally lower than those observed after the first dose.

Unsolicited adverse events occurring within 28 days of vaccination were reported in 44% and 45% of subjects who received FLUARIX QUADRIVALENT (n = 6,006) and the comparator vaccine (n = 6,012), respectively. Serious adverse events (SAEs) occurring during the study period (6 to 8 months) were reported in 3.6% of subjects who received FLUARIX QUADRIVALENT and in 3.3% of subjects who received the comparator vaccine.

In a clinical trial (NCT01196988) in which 915 children (3 through 17 years of age) received FLUARIX QUADRIVALENT, the related unsolicited adverse reactions that occurred most frequently (≥ 0.1%), following administration of FLUARIX QUADRIVALENT, included injection site pruritus and rash.

Concomitant Administration with Zoster Vaccine Recombinant, Adjuvanted (SHINGRIX)

In an open-label, randomized trial (NCT01954251), adults aged 50 years and older (median 63 years, range 50 to 92 years) received FLUARIX QUADRIVALENT and SHINGRIX at Month 0 and SHINGRIX at Month 2 (n = 413), or FLUARIX QUADRIVALENT at Month 0 and SHINGRIX at Months 2 and 4 (n = 415). Information about solicited local and systemic adverse reactions was collected using diary cards for 7 days (day of vaccination and the next 6 days). The rates of the solicited, systemic adverse reactions of fatigue, headache, myalgia, shivering, and fever (≥37.5°C) reported in subjects receiving FLUARIX QUADRIVALENT and SHINGRIX concomitantly were similar to those observed with SHINGRIX alone, and higher than when FLUARIX QUADRIVALENT was given alone.

6.2 Postmarketing Experience

The following adverse reactions have been identified during post approval use of

FLUARIX or FLUARIX QUADRIVALENT. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to the vaccine.

Blood and Lymphatic System Disorders

Lymphadenopathy.

Cardiac Disorders

Tachycardia.

Ear and Labyrinth Disorders

Vertigo.

Eye Disorders

Conjunctivitis, eye irritation, eye pain, eye redness, eye swelling, eyelid swelling.

Gastrointestinal Disorders

Abdominal pain or discomfort, nausea, swelling of the mouth, throat, and/or tongue.

General Disorders and Administration Site Conditions

Asthenia, chest pain, chills, influenza-like illness, feeling hot, injection site mass, injection site reaction, injection site warmth, body aches.

Immune System Disorders

Anaphylactic reaction including shock, anaphylactoid reaction, hypersensitivity, serum sickness.

Infections and Infestations

Injection site abscess, injection site cellulitis, pharyngitis, rhinitis, tonsillitis.

Musculoskeletal and Connective Tissue Disorders

Pain in extremity.

Nervous System Disorders

Convulsion, dizziness encephalomyelitis, facial palsy, facial paresis, Guillain-Barré syndrome, hypoesthesia, myelitis, neuritis, neuropathy, paresthesia, syncope.

Respiratory, Thoracic, and Mediastinal Disorders

Asthma, bronchospasm, cough, dyspnea, respiratory distress, stridor.

Skin and Subcutaneous Tissue Disorders

Angioedema, erythema, erythema multiforme, facial swelling, pruritus, rash, Stevens-Johnson syndrome, sweating, urticaria.

Vascular Disorders

Henoch-Schönlein purpura, vasculitis.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Available data from a pregnancy registry do not suggest an increased risk of major birth defects and miscarriage in individuals who received FLUARIX *(see Data)*. Data from women vaccinated with FLUARIX QUADRIVALENT are applicable to FLUARIX because both vaccines are manufactured using the same process and have overlapping compositions.

A developmental toxicity study was performed in female rats administered FLUARIX prior to mating and during gestation. The dose was 0.1 mL on each of 5 occasions (a single human dose is 0.5 mL). The study revealed no evidence of impaired female fertility or harm to the fetus due to FLUARIX *(see Data)*.

Clinical Considerations

Disease-Associated Maternal and/or Embryo/Fetal Risk: Pregnant women infected with seasonal influenza are at increased risk of severe illness associated with influenza infection compared with non-pregnant women. Pregnant women with influenza may be at increased risk for adverse pregnancy outcomes, including preterm labor and delivery.

Data

Human Data: A pregnancy exposure registry (2014 to 2019) included 437 prospective reports of exposure to FLUARIX QUADRIVALENT or FLUARIX, in the United States. After excluding pregnancies lost to follow-up (n = 322), those with an unknown outcome (n = 5), and those ongoing at time of last contact (n = 26), there were 84 pregnancies with exposure within 28 days prior to conception or during pregnancy and with known outcomes which included 1 spontaneous abortion, 1 stillbirth and 3 major birth defects. Among the 84 reports with known pregnancy outcomes, 17 individuals were exposed to FLUARIX QUADRIVALENT in the first trimester with 1 spontaneous abortion with no apparent birth defect and 1 stillbirth with no apparent birth defect reported; 34 individuals were exposed to FLUARIX QUADRIVALENT in the second trimester with 3 major birth defects reported; 21 individuals were exposed to FLUARIX QUADRIVALENT in the third trimester with no major birth defects reported; and 12 individuals were exposed to FLUARIX QUADRIVALENT at an unknown time in pregnancy with no major birth defects reported.

Animal Data: In a developmental toxicity study, the effect of FLUARIX on embryo-fetal and pre-weaning development was evaluated in pregnant rats. Animals were administered FLUARIX by intramuscular injection once prior to gestation, and during the period of organogenesis (gestation Days 6, 8, 11, and 15), 0.1 mL/rat/occasion. No adverse effects on mating, female fertility, pregnancy, parturition, lactation parameters, and embryo-fetal or pre-weaning development were observed. There were no vaccine-related fetal malformations or other evidence of teratogenesis.

8.2 Lactation

Risk Summary

It is not known whether FLUARIX is excreted in human milk. Data are not available to assess the effects of FLUARIX on the breastfed infant or on milk production/excretion. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for FLUARIX and any potential adverse effects on the breastfed child from FLUARIX or from the underlying maternal condition. For preventive vaccines, the underlying maternal condition is susceptibility to disease prevented by the vaccine.

8.4 Pediatric Use

Safety and effectiveness of FLUARIX in children younger than 6 months have not been established.

8.5 Geriatric Use

A randomized, single-blind, active-controlled trial evaluated immunological non-inferiority in a cohort of subjects aged 65 years and older who received FLUARIX (N = 606) or another U.S.-licensed trivalent, inactivated influenza vaccine (N = 604) (Sanofi Pasteur SA). In subjects receiving FLUARIX or the comparator vaccine, geometric mean antibody titers (GMTs) post-vaccination were lower in geriatric subjects than in younger subjects (aged 18 through 64 years). FLUARIX was non-inferior to the comparator vaccine for each of the 3 influenza strains based on mean antibody titers and seroconversion rates. *[See Clinical Studies (14.2).]* Solicited local and general adverse events were similar for FLUARIX and the comparator vaccine among geriatric subjects (Table 3). For both vaccines, the frequency of solicited events in subjects aged 65 years and older was lower than in younger subjects (Table 3). *[See Adverse Reactions (6.1).]*

11 DESCRIPTION

FLUARIX, Influenza Vaccine, is a sterile colorless and slightly opalescent injectable suspension for intramuscular use. FLUARIX is a vaccine prepared from influenza viruses propagated in embryonated chicken eggs. Each of the influenza viruses is produced and purified separately. After harvesting the virus-containing fluids, each influenza virus is concentrated and purified by zonal centrifugation using a linear sucrose density gradient solution containing detergent to disrupt the viruses. Following dilution, the vaccine is further purified by diafiltration. Each influenza virus solution is inactivated by the consecutive effects of sodium deoxycholate and formaldehyde leading to the production of a "split virus." Each split inactivated virus is then suspended in sodium phosphate-buffered isotonic sodium chloride solution. The vaccine is formulated from the 3 split inactivated virus solutions.

FLUARIX has been standardized according to U.S. Public Health Service (USPHS) requirements for the 2025-2026 influenza season and is formulated to contain 45 micrograms (mcg) hemagglutinin (HA) per 0.5-mL dose, in the recommended ratio of 15 mcg HA of each of the following 3 strains: A/Victoria/4897/2022 (H1N1) IVR-238, A/Croatia/10136RV/2023 (H3N2) X-425A, and B/Austria/1359417/2021 BVR-26 (B-Victoria lineage).

FLUARIX is formulated without preservatives. FLUARIX does not contain thimerosal. Each 0.5-mL dose also contains octoxinol-10 (TRITON X-100) ≤0.085 mg, α-tocopheryl hydrogen succinate ≤0.1 mg, and polysorbate 80 (Tween 80) ≤0.415 mg. Each dose

may also contain residual amounts of hydrocortisone ≤0.0015 mcg, gentamicin sulfate ≤0.15 mcg, ovalbumin ≤0.05 mcg, formaldehyde ≤5 mcg, and sodium deoxycholate ≤50 mcg from the manufacturing process.

The tip cap and rubber plunger stopper of the prefilled syringe are not made with natural rubber latex.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Specific levels of hemagglutination-inhibition (HI) antibody titer post-vaccination with inactivated influenza virus vaccines have not been correlated with protection from influenza illness but the HI antibody titers have been used as a measure of vaccine activity. In some human challenge trials, HI antibody titers of ≥1:40 have been associated with protection from influenza illness in up to 50% of subjects.[1,2] Antibody against one influenza virus type or subtype confers little or no protection against another virus. 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 virological basis for seasonal epidemics and the reason for the usual replacement of one or more new strains in each year's influenza vaccine.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

FLUARIX has not been evaluated for carcinogenic or mutagenic potential or for impairment of fertility in males.

14 CLINICAL STUDIES

14.1 Efficacy against Influenza

Efficacy Trial in Adults

The efficacy of FLUARIX was evaluated in Trial 3, a randomized, double-blind, placebo-controlled trial conducted in 2 European countries during the 2006-2007 influenza season. Efficacy of FLUARIX, containing A/New Caledonia/20/1999 (H1N1), A/Wisconsin/67/2005 (H3N2), and B/Malaysia/2506/2004 influenza strains, was defined as the prevention of culture-confirmed influenza A and/or B cases, for vaccine antigenically matched strains, compared with placebo. Healthy subjects aged 18 through 64 years (mean: 39.9 years) were randomized (2:1) to receive FLUARIX (N = 5,103) or placebo (N = 2,549) and monitored for influenza-like illnesses (ILI) starting 2 weeks post-vaccination and lasting for approximately 7 months. In the overall population, 60% of subjects were female and 99.9% were white. Culture-confirmed influenza was assessed by active and passive surveillance of ILI. Influenza-like illness was defined as at least one general symptom (fever ≥100°F and/or myalgia) and at least one respiratory symptom (cough and/or sore throat). After an episode of ILI, nose and throat swab samples were collected for analysis; attack rates and vaccine efficacy were calculated

(Table 6).

Table 6. FLUARIX: Attack Rates and Vaccine Efficacy against Culture-Confirmed Influenza A and/or B in Adults Aged 18 through 64 Years[a] (Total Vaccinated Cohort)

			Attack Rates (n/N)	Vaccine Efficacy		
	N	n	%	%	Lower Limit	Upper Limit
Antigenically Matched Strains[b]						
FLUARIX	5,103	49	1.0	66.9[c]	51.9	77.4
Placebo	2,549	74	2.9	–	–	–
All Culture-Confirmed Influenza (Matched, Unmatched, and Untyped)[d]						
FLUARIX	5,103	63	1.2	61.6[c]	46.0	72.8
Placebo	2,549	82	3.2	–	–	–

[a] Trial 3: NCT00363870.
[b] There were no vaccine matched culture-confirmed cases of A/New Caledonia/20/1999 (H1N1) or B/Malaysia/2506/2004 influenza strains with FLUARIX or placebo.
[c] Vaccine efficacy for FLUARIX exceeded a pre-defined threshold of 35% for the lower limit of the 2-sided 95% CI.
[d] Of the 22 additional cases, 18 were unmatched and 4 were untyped; 15 of the 22 cases were A (H3N2) (11 cases with FLUARIX and 4 cases with placebo).

In a post-hoc, exploratory analysis by age, vaccine efficacy (against culture-confirmed influenza A and/or B cases, for vaccine antigenically matched strains) in subjects aged 18 through 49 years was 73.4% (95% CI: 59.3, 82.8) [number of influenza cases: FLUARIX (n = 35/3,602) and placebo (n = 66/1,810)]. In subjects aged 50 through 64 years, vaccine efficacy was 13.8% (95% CI: -137.0, 66.3) [number of influenza cases: FLUARIX (n = 14/1,501) and placebo (n = 8/739)]. As the trial lacked statistical power to evaluate efficacy within age subgroups, the clinical significance of these results is unknown.

Efficacy Trial in Children

The efficacy of FLUARIX QUADRIVALENT was evaluated in Trial 5, a randomized, observer-blind, non-influenza vaccine-controlled trial conducted in 13 countries in Asia, Europe, and Central America during the 2011-2012 and 2012-2013 Northern Hemisphere influenza seasons, and from 2012 to 2014 during influenza seasons in subtropical countries. Healthy subjects aged 6 through 35 months (mean age: 22 months) were randomized (1:1) to receive FLUARIX QUADRIVALENT (n = 6,006) or a non-influenza control vaccine (n = 6,012). In the overall population, 51% were male; 27% were white, 45% were Asian, and 28% were of other racial/ethnic groups. Children aged 12 months and older with no history of influenza vaccination and children younger than 12 months received 2 doses of FLUARIX QUADRIVALENT or the Non-Influenza Active Comparator vaccine approximately 28 days apart. Children aged 12 months and older with a history of influenza vaccination received 1 dose. Data for FLUARIX QUADRIVALENT are relevant to FLUARIX because both vaccines are manufactured using the same process and have overlapping compositions.

The influenza virus strain composition of FLUARIX QUADRIVALENT administered in each

of the 5 study cohorts followed the World Health Organization (WHO) recommendations (which included 2nd B strain from 2012 onwards) for each influenza season associated with a particular cohort.

Efficacy of FLUARIX QUADRIVALENT was assessed for the prevention of reverse transcriptase polymerase chain reaction (RT-PCR)-confirmed influenza A and/or B disease, due to any seasonal influenza strain, compared with non-influenza control vaccines. Influenza disease included episodes of influenza-like illness (ILI, i.e., fever ≥100.4°F with any of the following: cough, runny nose, nasal congestion, or breathing difficulty) or a consequence of influenza virus infection (acute otitis media or lower respiratory illnesses). Among subjects with RT-PCR-positive influenza A and/or B disease, subjects were further prospectively classified based on the presence of adverse outcomes associated with influenza infection: fever >102.2°F, physician-diagnosed acute otitis media, physician-diagnosed lower respiratory tract illness, physician-diagnosed serious extra-pulmonary complications, hospitalization in the intensive care unit, or supplemental oxygen required for more than 8 hours. Subjects were monitored for influenza disease by passive and active surveillance starting 2 weeks post-vaccination and lasting for approximately 6 months. After an episode of ILI, lower respiratory illness, or acute otitis media, nasal swabs were collected and tested for influenza A and/or B by RT-PCR. All RT-PCR-positive specimens were further tested in cell culture and by antigenic characterization to determine whether the viral strains matched those in the vaccine. Vaccine efficacy for subjects with RT-PCR confirmed and culture-confirmed vaccine matching strains (According-to-Protocol (ATP) cohort for efficacy – time to event) is presented in Table 7.

Table 7. Attack Rates and Vaccine Efficacy against Influenza A and/or B in Children Aged 6 through 35 Months[a] (ATP Cohort for Efficacy – Time to Event)

			Attack Rates (n/N)	Vaccine Efficacy		
	N[b]	n[c]	%	%	Lower Limit	Upper Limit
All RT-PCR-Confirmed Influenza						
FLUARIX QUADRIVALENT	5,707	344	6.03	49.8	41.8[d]	56.8
Non-Influenza Comparator[e,f]	5,697	662	11.62	-	-	-
All Culture-Confirmed Influenza						
FLUARIX QUADRIVALENT	5,707	303	5.31	51.2	44.1[g]	57.6
Non-Influenza Comparator[e,f]	5,697	602	10.57	-	-	-
All Antigenically Matched Culture-Confirmed Influenza						
FLUARIX QUADRIVALENT	5,707	88	1.54	60.1	49.1[h]	69.0
Non-Influenza Comparator[e,f]	5,697	216	3.79	-	-	-

ATP = According-to-Protocol; RT-PCR = Reverse Transcriptase Polymerase Chain Reaction.

[a] Trial 5: NCT01439360.

[b] Number of subjects in the ATP cohort for efficacy – time to event, which included subjects who met all eligibility criteria, who were followed for efficacy and complied with the study protocol until the influenza-like episode.
[c] Number of subjects who reported at least one case in the reporting period.
[d] Vaccine efficacy for FLUARIX QUADRIVALENT met the pre-defined criterion for the lower limit of the 2-sided 97.5% CI (>15% for all influenza).
[e] Children younger than 12 months: pneumococcal 13-valent conjugate vaccine [Diphtheria CRM197 Protein] (Wyeth Pharmaceuticals, Inc.).
[f] Children 12 months and older: HAVRIX (Hepatitis A Vaccine) for those with a history of influenza vaccination; or HAVRIX (Dose 1) and a varicella vaccine (U.S. Licensed Manufactured by Merck & Co., Inc. or Non-U.S. Licensed Manufactured by GlaxoSmithKline Biologicals) (Dose 2) for those with no history of influenza vaccination.
[g] Vaccine efficacy for FLUARIX QUADRIVALENT met the pre-defined criterion of >10% for the lower limit of the 2-sided 95% CI.
[h] Vaccine efficacy for FLUARIX QUADRIVALENT met the pre-defined criterion of >15% for the lower limit of the 2-sided 95% CI.

The vaccine efficacy against RT-PCR-confirmed influenza associated with adverse outcomes was 64.6% (97.5% CI 53.2%, 73.5%). The vaccine efficacy against RT-PCR-confirmed influenza associated with adverse outcomes due to A/H1N1, A/H3N2, B/Victoria, and B/Yamagata was 71.4% (95% CI 48.5%, 85.2%), 51.3% (95% CI 32.7%, 65.2%), 86.7% (95% CI 52.8%, 97.9%), and 68.9% (95% CI 50.6%, 81.2%), respectively.

For RT-PCR-confirmed influenza cases associated with adverse outcomes, the incidence of the specified adverse outcomes is presented in Table 8.

Table 8 . Incidence of Adverse Outcomes Associated with RT-PCR-Positive Influenza in Children Aged 6 through 35 Months[a] (ATP Cohort for Efficacy-Time to Event)[b]

Influenza-Associated Symptom[e]	FLUARIX QUADRIVALENT n = 5,707			Non-Influenza Active Comparator[c,d] n = 5,697		
	Number of Events	Number of Subjects[f]	%	Number of Events	Number of Subjects[f]	%
Fever >102.2°F/39°C	62	61	1.1	184	183	3.2
Acute otitis media (AOM)[g]	5	5	0.1	15	15	0.3
Physician-diagnosed lower respiratory tract illness[h]	28	28	0.5	62	61	1.1
Physician-diagnosed serious extra-pulmonary	2	2	0	3	3	0.1

complications[i]						
Hospitalization in the intensive care unit	0	0	0	0	0	0
Supplemental oxygen required for more than 8 hours	0	0	0	0	0	0

ATP = According-to-Protocol; RT-PCR = Reverse transcriptase polymerase chain reaction.

[a] Trial 5: NCT01439360.

[b] Number of subjects in the ATP cohort for efficacy – time to event, which included subjects who met all eligibility criteria, who were followed for efficacy and complied with the study protocol until the influenza-like episode.

[c] Children younger than 12 months: pneumococcal 13-valent conjugate vaccine [Diphtheria CRM197 Protein] (Wyeth Pharmaceuticals, Inc.).

[d] Children 12 months and older: HAVRIX (Hepatitis A Vaccine) for those with a history of influenza vaccination; or HAVRIX (Dose 1) and a varicella vaccine (U.S. Licensed Manufactured by Merck & Co., Inc. or Non-U.S. Licensed Manufactured by GlaxoSmithKline Biologicals) (Dose 2) for those with no history of influenza vaccination.

[e] Subjects who experienced more than one adverse outcome, each outcome was counted in the respective category.

[f] Number of subjects with at least one event in a given category.

[g] Analyses considered AOM cases confirmed by otoscopy.

[h] Pneumonia, lower respiratory tract infection, bronchiolitis, bronchitis, or croup infection as per final diagnosis by physician.

[i] Includes myositis, encephalitis or other neurologic condition including seizure, myocarditis/pericarditis or other serious medical condition as per final diagnosis by physician.

14.2 Immunological Evaluation

In Trial 2, a randomized, single-blind, active-controlled U.S. trial, immunological non-inferiority of FLUARIX (N = 923) was compared with FLUZONE (N = 922), a U.S.-licensed trivalent, inactivated influenza vaccine (Sanofi Pasteur SA). Subjects aged 18 through 64 years and 65 years and older were evaluated for immune responses to each of the vaccine antigens 21 days following vaccination *[see Use in Specific Populations (8.5)]*. In the overall population, 59% of subjects were female and 91% were white. The co-primary immunogenicity endpoints were GMTs of serum HI antibodies and the percentage of subjects who achieved seroconversion, defined as at least a 4-fold increase in serum HI titer over baseline to ≥1:40, following vaccination. The primary immunogenicity analyses were performed on the According-to-Protocol (ATP) cohort which included all eligible and evaluable subjects with results of at least one serological assay. For each of the influenza antigens, the GMTs and the percentage of subjects who achieved seroconversion are presented in Table 9. FLUARIX was non-inferior to the comparator influenza vaccine based on antibody GMTs (upper limit of the 2-sided 95% CI for the GMT ratio [comparator influenza vaccine/FLUARIX] ≤1.5) and seroconversion rates (upper limit of the 2-sided 95% CI on difference of the comparator influenza vaccine minus FLUARIX ≤10%).

Table 9. Immune Responses 21 Days after Vaccination with FLUARIX Compared with Comparator Influenza Vaccine in Adults Aged 18 Years and Older[a] (ATP Cohort)

	FLUARIX n = 858 to 866 (95% CI)		Comparator Influenza Vaccine n = 846 to 854 (95% CI)	
GMTs	**Pre-Vaccination**	**Post-Vaccination**	**Pre-Vaccination**	**Post-Vaccination**
Anti-H1	27.9 (25.6, 30.5)	138.0 (125.2, 152.1)	29.1 (26.6, 31.7)	92.0 (84.5, 100.3)
Anti-H3	16.3 (15.1, 17.6)	121.6 (110.5, 133.7)	16.5 (15.4, 17.6)	114.0 (104.4, 124.5)
Anti-B	47.7 (44.1, 51.6)	231.9 (215.4, 249.6)	54.1 (49.9, 58.6)	273.7 (253.4, 295.7)
Seroconversion[b]	**% (95% CI) Post-Vaccination**		**% (95% CI) Post-Vaccination**	
A/New Caledonia/20/99 (H1N1)	45.7 (42.3, 49.1)		33.8 (30.6, 37.1)	
A/New York/55/2004 (H3N2)	67.1 (63.9, 70.3)		65.5 (62.2, 68.7)	
B/Jiangsu/10/2003	52.7 (49.3, 56.1)		53.8 (50.4, 57.2)	

Comparator influenza vaccine manufactured by Sanofi Pasteur SA.

ATP = According-to-protocol; GMT = Geometric mean antibody titer; CI = Confidence Interval; H1 = A/New Caledonia/20/99 (H1N1); H3 = A/New York/55/2004 (H3N2) for FLUARIX and A/California/7/2004 (H3N2) for comparator influenza vaccine; B = B/Jiangsu/10/2003.

ATP cohort included all eligible and evaluable subjects with results of at least one serological assay.

[a] Trial 2: NCT00197288.

[b] Seroconversion defined as at least a 4-fold increase in serum titers of HI antibodies to ≥1:40.

14.3 Concomitant Administration with Zoster Vaccine Recombinant, Adjuvanted (SHINGRIX)

In an open-label, randomized clinical trial (NCT01954251) in adults aged 50 years and older, there was no evidence for interference in antibody responses (HI antibodies and anti-gE antibodies) to FLUARIX QUADRIVALENT or the coadministered vaccine, SHINGRIX *[see Adverse Reactions (6.1)]*.

15 REFERENCES

1. Hannoun C, Megas F, Piercy J. Immunogenicity and protective efficacy of influenza vaccination. *Virus Res.* 2004;103:133-138.
2. Hobson D, Curry RL, Beare AS, et al. The role of serum haemagglutination-inhibiting

antibody in protection against challenge infection with influenza A2 and B viruses. *J Hyg Camb.* 1972;70:767-777.

16 HOW SUPPLIED/STORAGE AND HANDLING

FLUARIX is supplied in 0.5-mL single-dose, disposable, prefilled TIP-LOK syringes (Luer Lock syringes) packaged without needles. TIP-LOK syringes are to be used with Luer Lock compatible needles. The tip cap and rubber plunger stopper of the prefilled syringe are not made with natural rubber latex.

NDC 58160-912-41 Syringe in Package of 10: NDC 58160-912-52

Store refrigerated between 2º and 8ºC (36º and 46ºF). Do not freeze. Discard if the vaccine has been frozen. Store in the original package to protect from light.

17 PATIENT COUNSELING INFORMATION

Provide the following information to the vaccine recipient or guardian:

- Inform of the potential benefits and risks of immunization with FLUARIX.
- Educate regarding potential side effects, emphasizing that: (1) FLUARIX contains non-infectious killed viruses and cannot cause influenza and (2) FLUARIX is intended to provide protection against illness due to influenza viruses only, and cannot provide protection against all respiratory illness.
- Give the Vaccine Information Statements, which are required by the National Childhood Vaccine Injury Act of 1986 to be given prior to each immunization. These materials are available free of charge at the Centers for Disease Control and Prevention (CDC) website (www.cdc.gov/vaccines).
- Instruct that annual revaccination is recommended.

Manufactured by **GlaxoSmithKline Biologicals**, Dresden, Germany,

a branch of **SmithKline Beecham Pharma GmbH & Co. KG**, Munich, Germany

Licensed by **GlaxoSmithKline Biologicals,** Rixensart, Belgium, US License 1617

Distributed by **GlaxoSmithKline,** Durham, NC 27701

FLX:22PI

PRINCIPAL DISPLAY PANEL

NDC 58160-912-52

FLUARIX

Influenza Vaccine

2025/2026 Formula

Rx only

GSK

For 6 Months of Age and Older

10 Disposable Single-Dose Prefilled TIP-LOK Syringes each containing **one 0.5-mL dose**

TIP-LOK syringes to be used with Luer Lock compatible needles

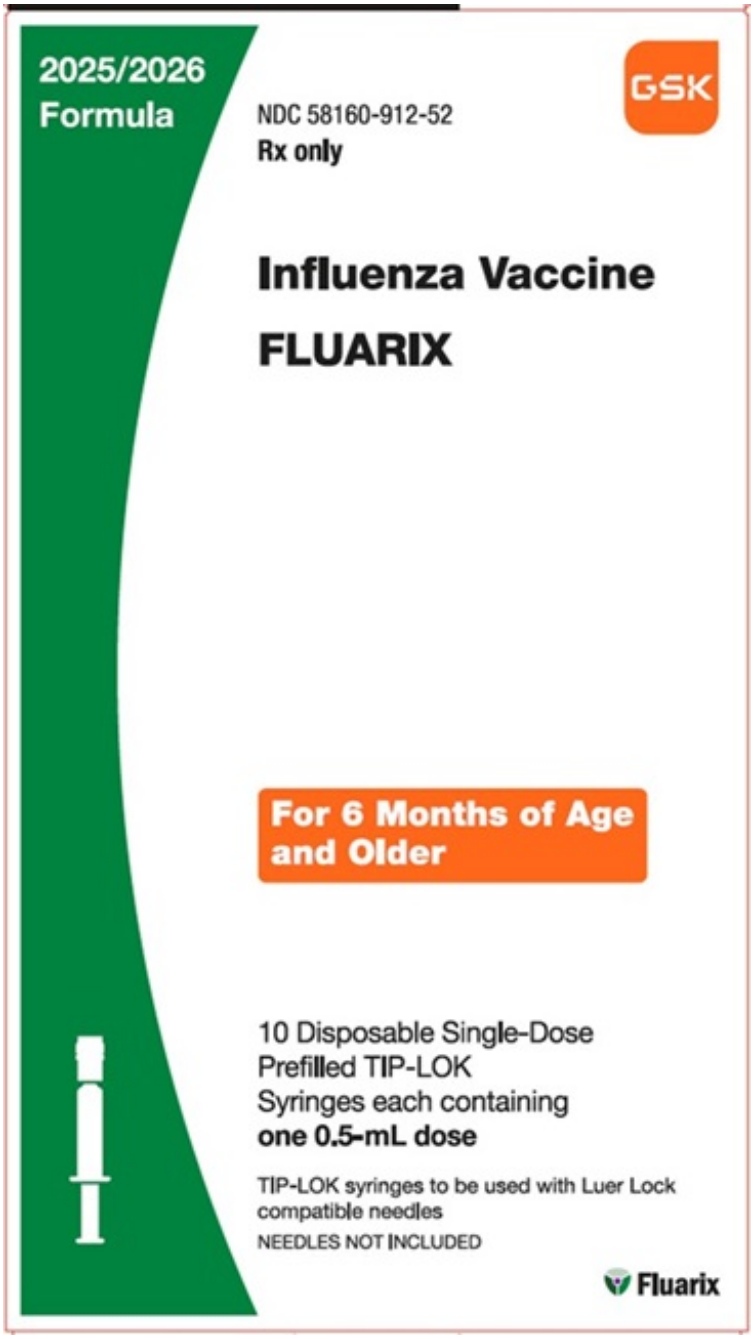
NEEDLES NOT INCLUDED

Fluarix

Made in Germany

Rev. 3/25

523645



FLUARIX 2025/2026

influenza virus vaccine suspension

Product Information			
Product Type	VACCINE	**Item Code (Source)**	NDC:58160-912
Route of Administration	INTRAMUSCULAR		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
INFLUENZA A VIRUS A/VICTORIA/4897/2022 IVR-238 (H1N1) ANTIGEN (FORMALDEHYDE INACTIVATED) (UNII: AU5C98U4BB) (INFLUENZA A VIRUS A/VICTORIA/4897/2022 IVR-238 (H1N1)	INFLUENZA A VIRUS A/VICTORIA/4897/2022 IVR-238 (H1N1) HEMAGGLUTININ	15 ug in 0.5 mL

HEMAGGLUTININ ANTIGEN (FORMALDEHYDE INACTIVATED) - UNII:C46XJT9FQ9)	ANTIGEN (FORMALDEHYDE INACTIVATED)	in 0.5 mL
INFLUENZA A VIRUS A/THAILAND/8/2022 IVR-237 (H3N2) ANTIGEN (FORMALDEHYDE INACTIVATED) (UNII: 6TU4EY6UNW) (INFLUENZA A VIRUS A/THAILAND/8/2022 IVR-237 (H3N2) HEMAGGLUTININ ANTIGEN (FORMALDEHYDE INACTIVATED) - UNII:Y86TJ6AR2X)	INFLUENZA A VIRUS A/THAILAND/8/2022 IVR-237 (H3N2) HEMAGGLUTININ ANTIGEN (FORMALDEHYDE INACTIVATED)	15 ug in 0.5 mL
INFLUENZA B VIRUS B/AUSTRIA/1359417/2021 BVR-26 ANTIGEN (FORMALDEHYDE INACTIVATED) (UNII: TZK7Q3545Q) (INFLUENZA B VIRUS B/AUSTRIA/1359417/2021 BVR-26 HEMAGGLUTININ ANTIGEN (FORMALDEHYDE INACTIVATED) - UNII:V4C2RVJ2EY)	INFLUENZA B VIRUS B/AUSTRIA/1359417/2021 BVR-26 HEMAGGLUTININ ANTIGEN (FORMALDEHYDE INACTIVATED)	15 ug in 0.5 mL

Inactive Ingredients

Ingredient Name	Strength
OCTOXYNOL-9 (UNII: 7JPC6Y25QS)	
.ALPHA.-TOCOPHEROL SUCCINATE, D- (UNII: LU4B53JYVE)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58160-912-52	10 in 1 CARTON		
1	NDC:58160-912-41	0.5 mL in 1 SYRINGE; Type 3: Prefilled Biologic Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125127	07/01/2025	06/30/2026

Labeler - GlaxoSmithKline Biologicals SA (372748392)

Revised: 7/2025 GlaxoSmithKline Biologicals SA