INFLUENZA VACCINE RECOMBINANT

Influenza Vaccine Recombinant

AHFS Class:

AHFS Class: Vaccines (80:12)

Make a selection below to quickly jump to a specific section.

Choose...

Alert:

On January 5, 2026, the US Department of Health and Human Services (HHS) announced the approval of a revised US childhood and adolescent immunization schedule ([Web]). Under the revised recommendations, CDC continues to organize the childhood immunization schedule in three distinct categories (Immunizations Recommended for All Children, Immunizations Recommended for Certain High-Risk Groups or Populations, and Immunizations Based on Shared Clinical Decision-Making) but changes individual vaccine placement within those categories. For additional information, see [Web] .

Introduction

Seasonal influenza vaccine recombinant (RIV3) stimulates active immunity to influenza virus infection.[1] Seasonal influenza vaccine recombinant is prepared using recombinant DNA technology and contains recombinant hemagglutinin (HA) proteins representing influenza virus types A and type B likely to circulate in the US during the upcoming influenza season.[1]

Uses

■ Prevention of Seasonal Influenza A and B Virus Infections

Influenza vaccine recombinant is used in individuals ≥9 years of age to stimulate active immunity for prevention of disease caused by influenza virus subtypes A and B represented in the vaccine.[1]

Each year, influenza vaccines are formulated based on recommendations from the FDA, Centers for Disease Control and Prevention (CDC), and other experts to determine the optimal viral antigen composition of the vaccines for the upcoming (current) influenza season.[100,101,102,112] All influenza vaccines available in the US for the 2025-26 season are trivalent formulations containing antigens representing influenza A (H1N1), influenza A (H3N2), and influenza B (Victoria lineage).[100,102]

Clinical Perspective

The American Academy of Pediatrics (AAP) and other organizations provide annual recommendations for the use of seasonal influenza vaccines in the US.[79,100,111,112] These organizations recommend annual influenza vaccination in *all* persons ≥6 months of age who do not have contraindications.[100,111,112] The Centers for Disease Control and Prevention (CDC) recommends the influenza vaccine for children after shared clinical decision-making with a healthcare provider.[602]

Various preparations of influenza virus vaccines are commercially available in the US, which differ based on method of manufacturer (egg-based versus cell culture-based), dose (standard versus high-dose), and route of administration (e.g., parenteral versus intranasal).[100] These preparations can be grouped into 3 broad categories: inactivated influenza vaccines (IIV3), recombinant influenza vaccine (RIV3), and live attenuated virus vaccine (LAIV3).[100] Inactivated influenza vaccines (IIV3) include standard-dose egg-based vaccines, a standard-dose cell culture-based influenza vaccine (ccIIV3), a high-dose egg-based vaccine (HD-IIV3), and an adjuvanted standard-dose egg-based vaccine (aIIV3).[100] For the 2025–26 season, egg-based influenza vaccines available in the US (i.e., vaccines other than ccIIV3 and RIV3) contain hemagglutinin derived from an influenza A/Victoria/4897/2022 (H1N1)pdm09-like virus; an influenza A/Croatia/10136RV/2023 (H3N2)-like virus; and an influenza B/Austria/1359417/2021 (B/Victoria lineage)-like virus.[100] For the 2025–26 season, cell culture-based inactivated (ccIIV3) and recombinant (RIV3) influenza vaccines in the US contain hemagglutinin derived from an influenza

A/Wisconsin/67/2022 (H1N1)pdm09-like virus; an influenza A/District of Columbia/27/2023 (H3N2)-like virus; and an influenza B/Austria/1359417/2021 (B/Victoria lineage)-like virus.[100]

ACIP states that all persons ≥6 months of age may receive an age-appropriate influenza vaccine with the exception of solid organ transplant recipients 18 through 64 years of age who are receiving immunosuppressive medication regimens; these individuals may receive either high-dose inactivated influenza vaccine (HD-IIV3) or adjuvanted inactivated influenza vaccine (aIIV3) as acceptable options (without a preference over other age-appropriate IIV3s or RIV3).[100] ACIP states that there are no preferential recommendations for any specific vaccine type when more than one licensed, recommended, and age-appropriate vaccine is available, with the exception of selection of influenza vaccines for individuals ≥65 years of age.[100] Because influenza vaccines are often less effective in older adults, the higher dose vaccines or adjuvanted vaccine is recommended in this population.[100] For the 2025-26 influenza season, ACIP recommends that adults ≥65 years preferentially receive trivalent high-dose inactivated influenza vaccine (HD-IIV3), trivalent recombinant influenza vaccine (RIV3), or trivalent adjuvanted inactivated influenza vaccine (aIIV3).[100] If none of these vaccines is available at an opportunity for vaccine administration, then any other age-appropriate influenza vaccine should be used.[100] Live attenuated influenza vaccine (LAIV3) should not be used in immunocompromised persons, persons with certain medical conditions, or persons receiving, having recently received, or about to receive influenza antiviral medications; LAIV also should not be used during pregnancy.[100] Patients should consult their healthcare provider about available flu vaccine options.[100]

The American College of Obstetricians and Gynecologists (ACOG) provides recommendations for annual influenza vaccine in pregnant individuals.[21] Because the risks associated with influenza infection are increased in both pregnant patients and their newborns, ACOG recommends that individuals who are or will be pregnant during the influenza season receive an inactivated or recombinant influenza vaccine as soon as the vaccines are available.[21]

The Center for Infectious Disease Research and Policy (CIDRAP) has established the Vaccine Integrity Project to provide evidence-based guidance on vaccines.[22] The Vaccine Integrity Project is an initiative dedicated to providing trusted, science-based information for informed vaccine choices.[22] A multi-disciplinary group of experts was convened by the Vaccine Integrity Project to independently review the available data on vaccine efficacy, effectiveness, and safety of COVID-19, influenza, and RSV immunizations for the 2025-2026 respiratory virus season.[22] A systematic review of 511 published studies (mostly observational) was conducted.[18] Results of the evidence review found that influenza vaccination was effective against symptomatic infection and hospitalization across age groups; pooled vaccine effectiveness against hospitalization was 48% in adults 18-64 years of age and 67% in children.[18] The recommended high-dose formulations were associated with added benefit in older adults.[18] For additional information, see [Web] .

Regarding the timing of influenza vaccination, ACIP states that for most individuals who need only 1 dose of influenza vaccine for the season, the vaccine should ideally be offered during September or October.[100] However, vaccination should continue after October and throughout the influenza season as long as influenza viruses are circulating and unexpired vaccine is available.[100] For most adults, vaccination during July and August generally should be avoided unless there is a concern that vaccination during the season might not be possible; however, vaccination during these months can be considered in children who require 2 doses, children who require only 1 dose but visit their healthcare provider during late summer before the start of the school year, and pregnant persons in the third trimester.[100]

Dosage and Administration

■ General

Pretreatment Screening

- Screen all individuals for contraindications and precautions to vaccination.[100,112]

Dispensing and Administration Precautions

- Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of influenza vaccine recombinant.[1]

■ Administration

Seasonal influenza vaccine recombinant is administered *only* by IM injection.[1] The vaccine should *not* be administered subcutaneously, intradermally, or IV.[1]

Syncope (vasovagal or vasodepressor reaction; fainting) may occur following vaccination; such reactions occur most frequently in adolescents and young adults.[134] Appropriate measures should be taken to decrease the risk of injury if a patient becomes weak or dizzy or loses consciousness (e.g., vaccinees should sit or lie down during and for 15 minutes after vaccination).[134] If syncope occurs, the patient should be observed until symptoms resolve.[134]

Influenza vaccine recombinant may be given simultaneously with other age-appropriate vaccines. When multiple vaccines are administered during a single health-care visit, each parenteral vaccine should be given using separate syringes and different injection sites.[134] Injection sites should be separated by at least 1 inch (if anatomically feasible) to allow appropriate attribution of any local adverse effects that may occur.[134]

IM Injection

IM injections of seasonal influenza vaccine recombinant should preferably be made into the deltoid muscle in adults.[1]

To ensure delivery into muscle, IM injections should be made at a 90° angle to the skin using a needle length appropriate for the individual's age and body mass, thickness of adipose tissue and muscle at the injection site, and injection technique.[134]

Prior to administration, influenza vaccine recombinant should be inspected visually for particulate matter and discoloration.[1] The vaccine should appear clear and colorless and should not be used if it appears discolored or contains particles.[1]

Single-dose prefilled syringes containing influenza vaccine recombinant should be inverted gently prior to affixing the appropriate size needle.[1]

Influenza vaccine recombinant should *not* be mixed with any other vaccine or solution.[1]

Dosage

Prevention of Seasonal Influenza A and B Virus Infections

Adults

The usual dosage of influenza vaccine recombinant for prevention of disease caused by seasonal influenza in adults is 0.5 mL administered IM as a single dose.[1]

Children 9–17 Years of Age

The usual dosage of influenza vaccine recombinant for prevention of disease caused by seasonal influenza in children 9–17 Years of age is 0.5 mL administered IM as a single dose.[1]

Special Populations

Geriatric Patients

The manufacturer makes no special population dosage recommendations.[1]

Cautions

Contraindications

- History of severe allergic reactions (e.g., anaphylaxis) to any component of the vaccine.[1]
- History of severe allergic reactions (e.g., anaphylaxis) to a previous dose of any recombinant influenza vaccine (quadrivalent or trivalent formulation).

Warnings/Precautions

Sensitivity Reactions

Anaphylaxis, anaphylactoid reactions, allergic reactions, and other forms of hypersensitivity have been reported during postmarketing experience.[1]

Prior to administration of influenza vaccine recombinant, the patient's immunization history regarding possible sensitivity reactions to the vaccine or vaccine components and vaccination-related adverse effects should be reviewed to identify any contraindications and assess the risks and benefits of the vaccine.[100,112,134] Appropriate medical treatment and supervision must be available for immediate use in case an anaphylactic reaction occurs.[1]

ACIP states a history of a severe allergic reaction (e.g., anaphylaxis) to any other influenza vaccine (i.e., any egg-based vaccine) is a precaution for the use of influenza vaccine recombinant.[100] If the vaccine is administered in such an instance, vaccination should occur in an inpatient or outpatient medical setting and should be supervised by a healthcare provider who is able to recognize and manage severe allergic reactions.[100] Although egg allergy is neither a contraindication nor precaution to the use of any influenza vaccine, there are contraindications and precautions related to allergies to vaccine components other than egg and to previous allergic reactions to influenza vaccines.[100]

Guillain-Barré Syndrome

If Guillain-Barré syndrome (GBS) occurred within 6 weeks after previous influenza vaccination, the manufacturer states that the decision to administer influenza vaccine recombinant should be based on careful consideration of potential benefits and risks.[1]

The 1976 swine influenza vaccine was associated with an increased frequency of GBS.[1] Evidence for a causal relationship between other influenza vaccines and GBS is inconclusive;[1] if an excess risk exists, it probably is slightly more than 1 additional case of GBS per 1 million vaccinees.[1]

ACIP states that a history of GBS within 6 weeks after receipt of any influenza vaccine is a precaution to the use of all influenza vaccines.[100]

Individuals with Altered Immunocompetence

Seasonal influenza vaccine recombinant may be administered to individuals immunosuppressed as the result of disease or immunosuppressive therapy.[1] However, the possibility that the immune response to the vaccine and efficacy may be reduced in these individuals should be considered.[1,134]

ACIP states that recombinant vaccines can be administered safely to individuals with altered immunocompetence.[134]

Syncope

Syncope (fainting) has been reported following vaccination with influenza vaccine recombinant.[1] Procedures should be in place to avoid injury from fainting.[1]

Individuals with Bleeding Disorders

Individuals who have bleeding disorders or are receiving anticoagulant therapy and/or their family members should be advised about the risk of hematoma from IM injections.[134]

ACIP states that IM vaccines may be given to individuals who have bleeding disorders or are receiving anticoagulant therapy if a clinician familiar with the patient's bleeding risk determines that the preparation can be administered IM with reasonable safety.[134] In these cases, a fine needle (23 gauge or smaller) should be used to administer the vaccine, and firm pressure applied to the injection site (without rubbing) for at least 2 minutes.[134] In individuals receiving therapy for hemophilia, IM vaccines can be administered shortly after a scheduled dose of such therapy.[134]

Concomitant Illness

The decision whether to administer or delay vaccination in an individual with a current or recent acute illness depends on the severity of symptoms and etiology of the illness.[134]

ACIP states that mild acute illness generally does not preclude vaccination.[134] However, moderate or severe acute illness (with or without fever) is a precaution for vaccination and vaccines should be deferred until the individual has recovered from the acute phase of the illness.[134] This precaution avoids superimposing adverse effects of the vaccine on the underlying illness or mistakenly concluding that a manifestation of the underlying illness resulted from vaccination.[134]

Limitations of Vaccine Effectiveness

Seasonal influenza vaccine recombinant may not protect all vaccine recipients from influenza.[1]

Specific Populations

Pregnancy

The manufacturer states that data are insufficient to assess the risk of using influenza vaccine recombinant in pregnant women.[1]

The available data from a post-licensure, observational, retrospective, safety surveillance study in 14,981 pregnant individuals found no evidence of a vaccine-associated increase in the risk of major birth defects and miscarriages with the quadrivalent form of influenza vaccine recombinant; patients were exposed to the vaccine during the 28 days prior to conception or during pregnancy.[1] The manufacturer states that data from the quadrivalent vaccine are relevant to the current trivalent formulation since both vaccines use the same manufacturing process and have overlapping compositions.[1]

A pregnancy registry has been established to monitor fetal outcomes of pregnant women exposed to seasonal influenza vaccine recombinant; clinicians are encouraged to contact the registry at 800-822-2463 or online at [Web] .[1]

Lactation

It is not known whether influenza vaccine recombinant is distributed into human milk.[1] Data are insufficient to assess the effects on the breast-fed infant or on milk production.[1]

The benefits of breast-feeding and the importance of the vaccine to the woman should be considered along with the potential adverse effects on the breast-fed child from the vaccine or from the underlying maternal condition (i.e., susceptibility to influenza infection).[1]

ACIP states that recombinant vaccines do not pose any unusual risks for women who are breast-feeding or their breast-fed infants.[134]

Pediatric Use

Safety and efficacy of influenza vaccine recombinant have not been established in individuals younger than 9 years of age.[1]

Diminished hemagglutination inhibition (HI) antibody responses have been observed in children 6 months of age through 8 years of age who received either the trivalent or quadrivalent influenza vaccine recombinant, suggesting that the vaccine would not be effective in children younger than 9 years of age.[1]

Geriatric Use

Clinical studies of influenza vaccine recombinant did not include sufficient numbers of patients 65 years of age and older to determine whether geriatric patients respond differently than younger adults.[1]

■ Common Adverse Effects

In children 9 through 17 years of age, the most common (≥10%) solicited injection-site adverse reaction was pain (34.4%); the most common (≥10%) solicited systemic adverse reactions were myalgia (19.3%), headache (18.5%), and malaise (16.1%).[1]

In adults 18 through 49 years of age, the most common (≥10%) injection-site adverse reaction was pain (37%); the most common (≥10%) solicited systemic adverse reactions were headache (15%), fatigue (15%), and muscle pain (11%).[1]

In adults 50 through 64 years of age, the most common (≥10%) injection site adverse reaction was pain (32%); the most common (≥10%) solicited systemic adverse reactions were headache (17%), fatigue (13%), and muscle pain (11%).[1]

In adults 65 years of age and older, the most common (≥10%) injection site adverse reaction was pain (19%); the most common (≥10%) solicited systemic adverse reactions were fatigue (13%) and headache (10%).[1]

Drug Interactions

■ Antiviral Agents

Antiviral agents used for the treatment or prevention of influenza (e.g., baloxavir marboxil, oseltamivir, peramivir, zanamivir) have no effect on the immune response to inactivated vaccines, including influenza vaccine recombinant.[134] Influenza vaccine recombinant may be administered to individuals receiving an influenza antiviral.

■ Immunosuppressive Agents

Immune responses to influenza vaccine recombinant may be reduced in individuals receiving immunosuppressive agents.[1,134]

Inactivated vaccines generally should be administered at least 2 weeks prior to initiation of immunosuppressive therapy and, because of possible suboptimal response, should not be administered during and for certain periods of time after immunosuppressive therapy is discontinued.[134]

■ Vaccines

Safety and immunogenicity of influenza vaccine recombinant administered concomitantly with age-appropriate inactivated or live vaccines have not been specifically studied to date.[1]

ACIP states that influenza vaccine recombinant may be administered concurrently with or at any interval before or after other age-appropriate vaccines, including live virus vaccines, toxoids, or inactivated or recombinant vaccines.[134] However, each parenteral vaccine should be administered at a different injection site and, if possible, the injection sites should be separated by at least 1 inch.[134]

COVID-19 Vaccines

An interim analysis of a study of 296 persons ≥65 years of age comparing concomitant administration of HD-IIV4 and a booster dose of an mRNA COVID-19 vaccine (administered in separate upper arm sites) with administration of either vaccine alone did not identify any safety concerns or any evidence of immune interference on influenza hemagglutination inhibition or SARS-CoV-2 binding antibody responses.[589] Local reactogenicity up to 21 days postvaccination was similar between the coadministration group and the group that received the mRNA COVID-19 vaccine alone.[589] However, systemic reactions were reported at similar frequencies in the coadministration and mRNA-1273 groups, with lower frequencies observed in participants who received QIV-HD alone.[589]

In a multicenter, randomized clinical study, 679 adult participants were recruited to receive concomitant administration of either an age-appropriate influenza vaccine or placebo along with their second dose of a COVID-19 vaccine (either an adenovirus viral vector COVID-19 vaccine, ChAdOx1, or an RNA COVID-19 vaccine, BNT162b2).[590] Injections were administered by IM injection in the upper arm, with one injection on each side for the concomitant administration recipients.[590] Analysis up to 21 days after vaccination, did not identify any safety concerns or evidence of immune interference on influenza hemagglutination inhibition or SARS-CoV-2 binding antibody responses.[590] The study found similar rates of local reactogenicity between the coadministration group and single vaccine administration group; however, systemic reactions were reported at similar frequencies in the coadministration and mRNA vaccine groups, with lower frequencies observed in participants who received QIV-HD alone.[590]

A retrospective analysis of self-reported vaccine data (v-safe [CDC's voluntary smartphone-based monitoring system]) from 92,023 patients 12 years of age and older that were registered as receiving a Moderna or Pfizer booster dose (monovalent) at the same time as an influenza vaccine, found that patients were slightly more likely to report any systemic reaction within 7 days of administration.[592] However, most reactions reported in this time period were generally mild (fatigue, headache, myalgia).[592]

Respiratory Syncytial Virus Vaccine

ACIP states that concomitant administration of RSV vaccines with other adult vaccines during the same visit is acceptable, but might increase local or systemic reactogenicity.[601] Concomitant administration of RSV and seasonal influenza vaccines met noninferiority criteria for immunogenicity with the exception of the FluA/Darwin H3N2 strain when the GSK RSV vaccine was administered concomitantly with adjuvanted quadrivalent inactivated influenza vaccine.[601] RSV and influenza antibody titers were somewhat lower with concomitant administration; however, the clinical significance of this is unknown.[601]

Description

Seasonal influenza vaccine recombinant contains recombinant hemagglutinin (HA) proteins from influenza viruses and is used to stimulate active immunity to influenza virus infection.[1] The vaccine is prepared using recombinant DNA technology and a continuous insect cell line (expresSF+®) derived from Sf9 cells of the fall armyworm (*Spodoptera frugiperda*) and a baculovirus vector.[1] Each of the influenza recombinant HA proteins is expressed individually, extracted from the cells using Triton® X-100, and further purified by column chromatography.[1] The manufacturing process for influenza vaccine recombinant does not use live influenza viruses and does not involve eggs.[1]

Each 0.5 mL of seasonal influenza vaccine recombinant for the 2025–2026 influenza season contains 45 mcg HA each of A/West Virginia/30/2022 (A/Wisconsin/67/2022 pdm09-like virus) (H1N1), A/District of Columbia/27/2023 (H3N2) and B/Austria/1359417/2021.[1] Each 0.5 mL of influenza vaccine recombinant also contains sodium chloride, monobasic

sodium phosphate, dibasic sodium phosphate, and polysorbate 20 and may also contain residual amounts of baculovirus and *S. frugiperda* cell proteins (no more than 19 mcg), baculovirus and cellular DNA (no more than 10 ng), and Triton® X-100 (no more than 100 mcg).[1] Influenza vaccine recombinant does not contain egg proteins, antibiotics, or preservatives; the single-dose syringes do not contain natural rubber latex.[1]

Following IM administration of influenza vaccine recombinant, the recombinant HA proteins contained in the vaccine act as antigens and induce a humoral immune response that can be measured by hemagglutination inhibition (HI) antibody.[1]

In a study in adults 18 through 49 years of age who received a single IM dose of trivalent influenza vaccine recombinant during the 2007–2008 influenza season, an immune response to the H1N1, H3N2, and B components of the vaccine was achieved in 78, 81, and 52% of vaccine recipients, respectively.[233] In these adults, estimated vaccine effectiveness against culture-confirmed influenza strains that closely matched the vaccine strains was 75% and estimated vaccine effectiveness without regard to match was 45% (96% of isolates did not match vaccine strains).[1,233] Immunogenicity of trivalent influenza vaccine recombinant in adults 50 years of age or older was evaluated in a randomized, controlled trial that compared antibody responses at 28 days after a single dose of the trivalent recombinant vaccine or a single dose of standard-dose trivalent influenza virus vaccine inactivated;[234] the trivalent recombinant vaccine met the predefined HI geometric mean titer (GMT) ratio success criterion for all 3 vaccine antigens.[234]

In a randomized, active-control study that evaluated the immune response to a single IM dose of quadrivalent influenza vaccine recombinant in adults 18 through 49 years of age during the 2014–2015 influenza season, the quadrivalent recombinant vaccine met the success criterion for GMTs for 3 of the 4 antigens, but not for the B/Victoria lineage antigen;[1] however, the HI response to the B/Victoria lineage antigen also was low in the active-control group that received quadrivalent influenza virus vaccine inactivated.[1] In a randomized, double-blind, active-control study evaluating efficacy of quadrivalent influenza vaccine recombinant in adults 50 years of age or older during the 2014–2015 influenza season, the quadrivalent recombinant vaccine was noninferior to standard-dose quadrivalent influenza virus vaccine inactivated.[1,574] The safety experience with influenza vaccine recombinant quadrivalent is relevant to influenza vaccine recombinant trivalent because both vaccines are manufactured using the same process and have overlapping compositions.[1]

Advice to Patients

The following information contains important points for the clinician to discuss with patients during counseling. For more comprehensive monographs suitable for distribution to the patient, please refer to the *AHFS Patient Medication Information* monographs available from MedlinePlus (in English and Spanish; written at a 6th- to 8th-grade reading level).

- Prior to administration of seasonal influenza vaccine recombinant, provide a copy of the appropriate CDC Vaccine Information Statement (VIS) to the patient or patient's legal representative.[1,20]
- Advise patient of the risks and benefits of influenza vaccine recombinant.[1]
- Advise patient that influenza vaccine recombinant contains noninfectious proteins that cannot cause influenza.[1]
- Advise patient that influenza vaccine recombinant provides protection against illness due to influenza viruses represented in the vaccine and cannot provide protection against all respiratory illness.[1]
- Stress importance of informing clinicians of any severe or life-threatening allergies, including any history of severe reaction after prior influenza vaccination.[1]
- Stress importance of informing clinicians of adverse effects.[1] Clinicians or individuals can report any adverse reactions that occur following vaccination to the Vaccine Adverse Event Reporting System (VAERS) at 800-822-7967 or [Web] .[1]
- Stress importance of informing clinician of existing or contemplated concomitant therapy, including prescription and OTC drugs, as well as concomitant illnesses (e.g., GBS).[1]
- Stress importance of women informing clinician if they are or plan to become pregnant or plan to breast-feed.[1]
- Inform patients of other important precautionary information.[1]

Additional Information

The American Society of Health-System Pharmacists, Inc. represents that the information provided in the accompanying monograph was formulated with a reasonable standard of care, and in conformity with professional standards in the field. Readers are advised that decisions regarding use of drugs are complex medical decisions requiring the independent, informed decision of an appropriate health care professional, and that the information contained in the monograph is provided for informational purposes only. The manufacturer's labeling should be consulted for more detailed information. The American Society of Health-System Pharmacists, Inc. does not endorse or recommend the use of any drug. The information contained in the monograph is not a substitute for medical care.

Preparations

Excipients in commercially available drug preparations may have clinically important effects in some individuals; consult specific product labeling for details.

Influenza Vaccine Recombinant

ROUTES	FORMS	STRENGTHS	BRAND NAMES	MANUFACTURER

Parenteral	*Injection, for IM use*	*45 mcg recombinant hemagglutinin each of FDA-specified influenza A (H1N1), influenza A (H3N2), and influenza B/Victoria lineage antigens per 0.5 mL*	*Flublok 2025-2025 Formula®*	*Sanofi Pasteur*

† Use is not currently included in the labeling approved by the US Food and Drug Administration.

Original Publication Date: November 01, 2013.
Database Extraction: 05/07/2026 19:15:09 +0000+

References

1. Sanofi Pasteur. Flublok® (influenza vaccine recombinant) sterile solution for intramuscular injection prescribing information. Swiftwater, PA; 2025 Jul.

18. Scott J, Abers MS, Marwah HK et al. Updated Evidence for Covid-19, RSV, and Influenza Vaccines for 2025-2026. N Engl J Med. 2025 Dec 4;393(22):2221-2242. doi: 10.1056/NEJMsa2514268. Epub 2025 Oct 29. PMID: 41160817.

20. US Centers for Disease Control and Prevention. Current vaccine information sheets. From CDC website.

21. American College of Obstetricians and Gynecologists. Influenza in pregnancy: prevention and treatment practice advisory August 2025. From ACOG website.

22. Center for Infectious Disease Research and Policy (CIDRAP). Vaccine Integrity Project. From the CIDRAP website.

79. American Academy of Pediatrics. Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger. From AAP website.

100. Grohskopf LA, Blanton LH, Ferdinands JM, Reed C, Dugan VG, Daskalakis DC. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2025–26 Influenza Season. MMWR Morb Mortal Wkly Rep 2025;74:500–507. DOI: http://dx.doi.org/10.15585/mmwr.mm7432a2.

101. Centers for Disease Control and Prevention (CDC). 2025-2026 flu season. Updated Jan 7,2026. From CDC website.

102. US Food and Drug Administration. Influenza vaccine composition for the 2025-2026 US influenza season. From the FDA website.

111. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP)—United States, 2025-26 Influenza Season Summary of Recommendations

112. American Academy of Pediatrics Committee on Infectious Diseases. Recommendations for Prevention and Control of Influenza in Children, 2025–2026: Policy Statement. Pediatrics. 2025; doi: 10.1542/peds.2025-073620

118. American College of Obstetricians and Gynecologists. Influenza vaccination during pregnancy. ACOG committee opinion N. 732. 2018 Apr. From ACOG website.

134. Kroger A, Bahta L, Hunter P. General best practice guidelines for immunization. Best practices guidance of the Advisory Committee on Immunization Practices (ACIP). From CDC website.

166. US Centers for Disease Control and Prevention. Epidemiology and prevention of vaccine-preventable diseases. 14th ed. Washington DC: Public Health Foundation; 2021. Updates may be available at CDC website.

233. Treanor JJ, El Sahly HM, King J, et al. Protective efficacy of a trivalent, insect cell-expressed, recombinant hemagglutinin protein vaccine (FluBlok) against culture confirmed influenza in healthy adults: a randomized, placebo-controlled trial. *Vaccine*. 2011; 29 (44): 7733-9.

234. Baxter R, Patriarca PA, Ensor K. Evaluation of the safety, reactogenicity and immunogenicity of FluBlok® trivalent recombinant baculovirus-expressed hemagglutinin influenza vaccine administered intramuscularly to healthy adults 50-64 years of age. *Vaccine*. 2011; 29:2272-8
PubMed

574. Dunkle LM, Izikson R, Patriarca P. Efficacy of Recombinant Influenza Vaccine in Adults 50 Years of Age or Older. *N Engl J Med*. 2017; 376:2427-2436
PubMed

589. Izikson R, Brune D, Bolduc JS, et al. Safety and immunogenicity of a high-dose quadrivalent influenza vaccine administered concomitantly with a third dose of the mRNA-1273 SARS-CoV-2 vaccine in adults aged ≥65 years: a phase 2, randomised, open-label study. Lancet Respir Med 2022;10:392–402. Epub Feb. 21, 2022.

590. Lazarus R, Baos S, Cappel-Porter H, er al. Safety and immunogenicity of concomitant administration of COVID-19 vaccines (ChAdOx1 or BNT162b2) with seasonal influenza vaccines in adults in the UK (ComFluCOV): a multicentre, randomised, controlled, phase 4 trial. Lancet 2021; 398: 2277–87.

592. Hause AM, Zhang B, Yue X, et al. Reactogenicity of Simultaneous COVID-19 mRNA Booster and Influenza Vaccination in the US. JAMA Netw Open. 2022;5(7):e2222241.

601. Melgar M, Britton A, Roper L et al. Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023. MMWR. 2023; 72:793-801.

602. Centers for Disease Control and Prevention. Child and Adolescent Immunization Schedule by Age. 2025.