NOW APPROVED
FOR PATIENTS
9 YEARS & OLDER[1]

HIGHER-DOSE PROTECTION WITH FLUBLOK
EVEN FOR YOUR PATIENTS WHO FEEL **UNSTOPPABLE**[1]

Flublok is a vaccine indicated for active immunization for the prevention of disease caused by influenza A virus subtypes and influenza type B virus represented by antigens contained in the vaccine. Flublok is approved for use in individuals 9 years of age and older.

- **3x** Recombinant technology with **3x MORE ANTIGEN** than standard-dose flu vaccines[1-3]*
- **RCT** Efficacy supported by data from **RANDOMIZED CONTROLLED TRIALS** in patients aged 18+[1,2,4]
- **ESTABLISHED SAFETY PROFILE**[1,4]

ACIP
RECOMMENDED FOR 65+[3]

Flublok is among the flu vaccines preferentially recommended by ACIP for those 65+ years vs unadjuvanted standard-dose flu vaccines.[3]

*Flublok contains 45 micrograms (mcg) of HA per strain vs 15 mcg of HA per strain in a standard-dose influenza vaccine.[1-3]

ACIP=Advisory Committee on Immunization Practices; HA=hemagglutinin.

IMPORTANT SAFETY INFORMATION

Do not administer Flublok to anyone with a history of severe allergic reactions (e.g., anaphylaxis) to any component of the vaccine.

Please see additional Important Safety Information throughout and full Prescribing Information.

Flublok®
Influenza Vaccine

FLUBLOK COMBINES THE ADVANTAGES OF RECOMBINANT TECHNOLOGY WITH A HIGHER ANTIGEN CONTENT[2,5*]

3x THE ANTIGEN[1-3]

Flublok contains 3x the HA antigen of cell- and egg-based standard-dose flu vaccines, which has been linked to greater immunogenicity.

MAY PROVIDE CROSS-PROTECTION[5]

Recombinant technology leads to a broader immune response and may provide cross-protection against drifted strains during mismatched seasons.[†]

ELIMINATES RISK OF ANTIGENIC MISMATCH DURING MANUFACTURING[5,6]

The only flu vaccine produced with recombinant technology, Flublok ensures identical antigenic match with WHO- and FDA-selected flu strains. Recombinant technology eliminates the risk of mutations that may occur with cell- or egg-based vaccines.

MAY INDUCE A MORE ROBUST ANTIBODY RESPONSE[7]

According to a study published by the CDC in January 2024, vaccination with a higher-dose recombinant flu vaccine may induce a more robust antibody response than egg-based standard-dose vaccines.

*Flublok contains 45 micrograms (mcg) of HA per strain vs 15 mcg of HA per strain in a standard-dose influenza vaccine.[1-3]

[†]Flublok is produced using a novel production platform in which recombinant HA is expressed in insect cells using a baculovirus expression vector system (BEVS). Recombinant HA antigens produced using BEVS have been shown to induce significantly higher levels of broadly cross-reactive antibodies against highly conserved regions of HA compared with egg-derived vaccines, which may potentially protect against drift-variant influenza viruses.[5]

CDC=Centers for Disease Control and Prevention; FDA=US Food and Drug Administration; WHO=World Health Organization.

IMPORTANT SAFETY INFORMATION

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

Please see additional Important Safety Information throughout and full Prescribing Information.

Flublok®
Influenza Vaccine

PIVOTAL TRIAL

IN A RANDOMIZED CONTROLLED TRIAL OF ADULTS AGED 50+

FLUBLOK PREVENTED 30% MORE FLU CASES THAN A STANDARD-DOSE INFLUENZA VACCINE[1,2*]

STUDY DESIGN[1,2]

- **Phase 3-4 randomized controlled trial** in adults aged 50+ (n≈9000) evaluated the efficacy of Flublok vs Fluarix during the 2014-2015 influenza season, in which A (H3N2) was predominant and antigenically mismatched[1,2]
- The primary endpoint was PCR–confirmed, protocol-defined influenza-like illness that occurred between 14 days or more after vaccination and the end of the influenza season and was caused by any influenza virus type or subtype[2]
- **Patients with comorbidities who received Flublok:** insulin-dependent diabetes: 3.9% (170); non-insulin-dependent diabetes: 10.8% (469); atherosclerotic cardiovascular disease: 30.5% (1320); condition requiring statin lipid-lowering therapy: 27.6% (1194); condition requiring thiazide diuretic: 7.7% (332); chronic obstructive pulmonary disease: 3.3% (144); acid reflux or peptic ulcer disease: 14.5% (629); depression: 18.2% (788)[2]

*Flublok (quadrivalent) was proven to prevent more flu in older adults than Fluarix (quadrivalent standard-dose vaccine). The efficacy of Flublok (quadrivalent) is relevant to Flublok (trivalent) because both vaccines are manufactured using the same process and have overlapping compositions.[1]

PROVEN TO HELP PREVENT MORE CASES OF THE FLU THAN FLUARIX IN ADULTS AGED 50+[1,2]

Flublok prevented more cases of influenza than a standard-dose vaccine and satisfied the primary criterion for non-inferiority and the prespecified exploratory superiority criterion.[2]

30% (95% CI: 10-47)

FEWER FLU CASES WITH FLUBLOK

Primary endpoint: Relative vaccine efficacy (rVE) against influenza due to ANY PCR-confirmed circulating strains[1,2]

43% (95% CI: 21-59)

FEWER FLU CASES WITH FLUBLOK

Secondary endpoint: rVE against influenza due to ANY culture-confirmed circulating strains[1,2]

CI=confidence interval; PCR=polymerase chain reaction.

SAFETY PROFILE IN ADULTS AGED 50+ WAS COMPARABLE TO STANDARD DOSE[1,2]

- Most common adverse events (≥10%) in the Flublok group in adults aged 50-64[2]:
  - -Injection-site reactions: tenderness (37%), pain (32%)
  - -Systemic adverse reactions: headache (17%), fatigue (13%), muscle pain (11%)

IMPORTANT SAFETY INFORMATION

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

Please see additional Important Safety Information throughout and full Prescribing Information.

Flublok®
Influenza Vaccine

PIVOTAL TRIAL

IN A RANDOMIZED CONTROLLED TRIAL OF ADULTS AGED 18-49

FLUBLOK PROVIDED EFFECTIVE FLU PROTECTION, EVEN IN A SEASON WITH SIGNIFICANT ANTIGENIC MISMATCH[1,4]

STUDY DESIGN

- Randomized, observer-blind, placebo-controlled trial to evaluate the protective efficacy and safety of Flublok (trivalent) against influenza in 4648 adults aged 18-49 years[1,4]
- The study was undertaken during the 2007-2008 influenza season, when there was significant mismatch between vaccine antigens and circulating viruses[4]
- Primary endpoint: CDC–defined influenza-like illness (ILI), defined by the presence of documented fever ≥100°F plus either sore throat or cough with positive culture for an influenza virus strain antigenically resembling a strain represented in Flublok. Vaccine efficacy against antigenically matched culture-confirmed CDC-defined ILI could not be determined reliably because 96% of the influenza isolates obtained were not antigenically matched to the strains represented in the vaccine[1]

ADDITIONAL EFFICACY ENDPOINTS[1]

44.6%
(95% CI: 18.8, 62.6)

FEWER FLU CASES WITH FLUBLOK
due to ANY culture-documented, CDC-defined ILI strain, regardless of match to the vaccine[1]

44.8%
(95% CI: 24.4, 60.0)

FEWER FLU CASES WITH FLUBLOK
due to ANY culture-confirmed ILI strain, regardless of match to the vaccine[1]

SYSTEMIC SYMPTOMS WITH FLUBLOK WERE COMPARABLE TO THOSE WITH PLACEBO[1,4]

- The most frequently reported systemic symptoms following vaccination were headache (15% with Flublok vs 16% with placebo) and fatigue (15% with Flublok vs 14% with placebo)[4]
- 76% of headache complaints were mild[4]
- Flublok was associated with local injection-site pain and muscle aches that were significantly more frequent than after saline placebo (38% vs 8%, respectively)[1,4]
- 94% of all pain complaints after Flublok were rated as mild[4]

IMPORTANT SAFETY INFORMATION

If Flublok is administered to immunocompromised persons, including those receiving immunosuppressive therapy, the immune response may be diminished.

Please see additional Important Safety Information throughout and full Prescribing Information.

Flublok®
Influenza Vaccine

IMMUNOGENICITY

FLUBLOK DEMONSTRATED A SIMILAR SAFETY PROFILE IN 9 TO 17-YEAR-OLDS VS 18 TO 49-YEAR-OLDS[1]*

STUDY DESIGN

- A phase 3 non-randomized, open-label, uncontrolled, multicenter study of 1308 participants aged 9 to 49 years[1]
- Primary objective was to demonstrate that vaccination with Flublok induced an immune response in children and adolescents aged 9 to 17 that was non-inferior to responses induced by Flublok in adults aged 18 to 49 for 4 viral strains at Day 29 post-vaccination[1]
- Immune response was assessed by hemagglutination inhibition (HI), geometric mean titers (GMTs), and seroconversion (SCR) rates[1]

IN PATIENTS AGED 9-17, FLUBLOK INDUCED A LEVEL OF IMMUNOGENICITY NON-INFERIOR TO THAT IN ADULTS AGED 18-49[1]

- The non-inferiority of HI immune responses induced by Flublok (quadrivalent) in patients aged 9 to 17 relative to patients aged 18 to 49 was **demonstrated for all 4 strains** (A/H1N1, A/H3N2, B/Victoria, and B/Yamagata)[1]*
- Non-inferiority was based on prespecified criteria (lower limit of the 2-sided 95% CIs of the ratios of GMTs between age groups [9-17 years/18-49 years] >0.667; lower limit of the 2-sided 95% CI of the difference in SCR rates > −10 at Day 29 post-vaccination)[1]

SAFETY IN PATIENTS AGED 9-17

- There were no significant observed differences in safety profile between the 9 to 17-year-old and 18 to 49-year-old populations[1]
- Most common adverse reactions in 9 to 17-year-olds[1]:
  - Injection-site reaction: pain (34.4%)
  - Systemic reactions: myalgia (19.3%), headache (18.5%), malaise (16.1%)

*Effectiveness of Flublok (quadrivalent) in children aged 9 to 17 is based on comparison to adults aged 18 to 49. The data for Flublok (quadrivalent) is relevant to Flublok (trivalent) because both vaccines are manufactured using the same process and have overlapping compositions.[1]

IMPORTANT SAFETY INFORMATION

Vaccination with Flublok may not protect all recipients.

Please see additional Important Safety Information throughout and full Prescribing Information.

Flublok®
Influenza Vaccine

IMPORTANT SAFETY INFORMATION AND REFERENCES

INDICATION

Flublok is a vaccine indicated for active immunization for the prevention of disease caused by influenza A virus subtypes and influenza type B virus represented by antigens contained in the vaccine. Flublok is approved for use in individuals 9 years of age and older.

IMPORTANT SAFETY INFORMATION

Do not administer Flublok to anyone with a history of severe allergic reactions (e.g., anaphylaxis) to any component of the vaccine.

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

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

If Flublok is administered to immunocompromised persons, including those receiving immunosuppressive therapy, the immune response may be diminished.

Vaccination with Flublok may not protect all recipients.

Syncope (fainting) has been reported following vaccination with Flublok. Procedures should be in place to avoid injury from fainting.

In children 9 through 17 years of age who received Flublok Quadrivalent, the most common solicited injection-site adverse reaction was pain; the most common solicited systemic adverse reactions were myalgia, headache, and malaise. In adults 18 through 64 years of age who received Flublok, the most common injection site adverse reaction was pain; the most common solicited systemic adverse reactions were headache, fatigue, and myalgia. In adults 65 years of age and older who received Flublok, the most common injection-site adverse reaction was pain; the most common solicited systemic adverse reactions were fatigue and headache. Other adverse reactions may occur.

Please see additional Important Safety Information throughout and full Prescribing Information.

References: 1. Flublok. Prescribing Information. Protein Sciences Corporation. **2.** Dunkle LM, Izikson R, Patriarca P, et al; PSC12 Study Team. Efficacy of recombinant influenza vaccine in adults 50 years of age or older. *N Engl J Med.* 2017;376(25):2427-2436. doi:10.1056/NEJMoa1608862 **3.** Grohskopf LA, Ferdinands JM, Blanton LH, Broder KR, Loehr J. Prevention and control of seasonal influenza with vaccines: recommendations of the Advisory Committee on Immunization Practices — United States, 2024–25 influenza season. *MMWR Recomm Rep.* 2024;73(5):1-25. doi:10.15585/mmwr.rr7305a1 **4.** Treanor JJ, El Sahly H, King J, et al. Protective efficacy of a trivalent recombinant hemagglutinin protein vaccine (Flublok®) against influenza in healthy adults: a randomized, placebo-controlled trial. *Vaccine.* 2011;29(44):7733-7739. doi:10.1016/j.vaccine.2011.07.128 **5.** Arunachalam AB, Post P, Rudin D. Unique features of a recombinant haemagglutinin influenza vaccine that influence vaccine performance. *NPJ Vaccines.* 2021;6(1):144. doi:10.1038/s41541-021-00403-7 **6.** Centers for Disease Control and Prevention. Influenza vaccines—United States, 2023–24 influenza season. Accessed March 27, 2025. https://archive.cdc.gov/#/details?url=https://www.cdc.gov/flu/professionals/acip/2022-2023/acip-table.htm **7.** Liu F, Gross FL, Joshi S, et al. Redirecting antibody responses from egg-adapted epitopes following repeat vaccination with recombinant or cell culture-based versus egg-based influenza vaccines. *Nat Commun.* 2024;15(1):254. doi:10.1038/s41467-023-44551-x

Flublok®
Influenza Vaccine

