HIGHER-DOSE PROTECTION WITH FLUBLOK

EVEN FOR YOUR PATIENTS WHO FEEL **UNSTOPPABLE**[1]

FOR PATIENTS 9 YEARS & OLDER[1]

FLUBLOK HAS BEEN SHOWN TO **HELP PROTECT PATIENTS AGED 18+ AGAINST FLU AND ITS COMPLICATIONS**[1,2]

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** **PROVEN TO PREVENT MORE FLU THAN STANDARD DOSE** in a randomized controlled trial of patients aged 50+[1,2†]
- **RWE** **REAL-WORLD EVIDENCE IN FLU HOSPITALIZATIONS** vs standard dose in patients aged 18+[4]
- **ESTABLISHED SAFETY PROFILE**[1,5]

ACIP RECOMMENDED[3]

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

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

†Flublok (quadrivalent) was proven to prevent 30% more flu cases in older adults than Fluarix (quadrivalent standard-dose vaccine) in a phase 3-4 randomized controlled trial of adults aged 50+ (N≈9000) during the 2014-2015 season. The primary endpoint was relative vaccine efficacy against influenza due to any PCR-confirmed circulating strains. The efficacy of Flublok (quadrivalent) is relevant to Flublok (trivalent) because both vaccines are manufactured using the same process and have overlapping compositions.[1]

ACIP=Advisory Committee on Immunization Practices; HA=hemagglutinin; PCR=polymerase chain reaction.

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.

Before administration, please see full Prescribing Information.



Flublok®
Influenza Vaccine

FLUBLOK COMBINES THE ADVANTAGES OF RECOMBINANT TECHNOLOGY WITH A HIGHER DOSE[2,6]

ELIMINATES RISK OF ANTIGENIC MISMATCH DURING MANUFACTURING[6,7]

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 can occur with cell- or egg-based vaccines.

MAY PROVIDE CROSS-PROTECTION[6]

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

3X THE ANTIGEN[†1-3]

Flublok contains 3x the hemagglutinin (HA) antigen content of cell- and egg-based standard-dose flu vaccines, which has been linked to greater immunogenicity.[†]

MAY INDUCE A MORE ROBUST IMMUNE RESPONSE[8]

Vaccination with a higher-dose recombinant flu vaccine may lead to a greater antibody response vs cell- and egg-based standard-dose vaccines.

FLUBLOK IS THE ONLY FLU VACCINE THAT DOES NOT USE THE INFLUENZA VIRUS IN ANY PART OF THE MANUFACTURING PROCESS[9‡]

*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.[6]

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

[‡]According to the CDC, getting a flu vaccine will not give you the flu.[10]

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. 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.

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Flublok® Influenza Vaccine

PIVOTAL TRIAL

IN A RANDOMIZED CONTROLLED TRIAL VS FLUARIX

30% RELATIVE REDUCTION IN PCR-CONFIRMED FLU IN ADULTS AGED 50+[1,2]

STUDY DESIGN[1,2]

- **Phase 3-4 randomized controlled trial** in adults aged 50+ (N≈9000) during the 2014-2015 influenza season, in which A (H3N2) was predominant and antigenically mismatched
- Patients were randomized 1:1 to receive **Flublok or Fluarix***
- **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 noninferiority 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.

SAFETY IN ADULTS

- Comparable safety profile to a standard-dose quadrivalent inactivated influenza vaccine in adults aged 50+[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 Flublok is administered to immunocompromised persons, including those receiving immunosuppressive therapy, the immune response may be diminished.

Please see additional Important Safety Information throughout.
Before administration, please see full Prescribing Information.

Flublok®
Influenza Vaccine

PIVOTAL TRIAL

IN PATIENTS AGED 18-49 YEARS

FLUBLOK: EFFECTIVE FLU PROTECTION, EVEN IN A SEASON WITH SIGNIFICANT ANTIGENIC MISMATCH[1,5]

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[1,5]
- The study was undertaken during the 2007-2008 influenza season, when there was significant mismatch between vaccine antigens and circulating viruses[5]
- Primary endpoint: CDC-defined influenza-like illness (ILI), defined by 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-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

44.6% (95% CI: 18.8, 62.6)

FEWER FLU CASES WITH FLUBLOK due to any culture-confirmed 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]

FLUBLOK WAS ASSOCIATED WITH PREVENTING CULTURE-CONFIRMED FLU DESPITE SIGNIFICANT ANTIGENIC MISMATCH BETWEEN THE VACCINE ANTIGENS AND CIRCULATING VIRUSES[1]

IMPORTANT SAFETY INFORMATION

Vaccination with Flublok may not protect all recipients.

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Flublok®
Influenza Vaccine

REAL-WORLD EVIDENCE

THE LARGEST RANDOMIZED REAL-WORLD FLU EFFECTIVENESS STUDY TO DATE[11,12]

STUDY DESIGN

- **Modified cluster randomized observational study** to evaluate Flublok vs standard-dose influenza vaccines[11]*
- **Study population: 1,630,328 members** of the Kaiser Permanente Northern California (KPNC) healthcare system aged 18-64 years[11]
- Evaluated over 2 flu seasons: 2018-2019 influenza season, when A (H1N1) was predominant until March 2019, when A (H3N2) viruses became predominant, and 2019-2020 influenza season, when A (H1N1) was predominant with B cocirculation[13-15]
- **Patients aged 50-64 with comorbid conditions:** asthma: 14% (96,307); diabetes: 18% (119,430); chronic obstructive pulmonary disease: 2% (13,357); coronary heart disease: 4% (25,496)[11]

*Flublok (quadrivalent) was proven to prevent more flu in older adults than quadrivalent standard-dose vaccines. The efficacy of Flublok (quadrivalent) is relevant to Flublok (trivalent) because both vaccines are manufactured using the same process and have overlapping compositions.[1,11]

FLUBLOK WAS ASSOCIATED WITH GREATER PROTECTION VS STANDARD-DOSE VACCINES[11]

15.3%
(95% CI: 5.9, 23.8)

FEWER FLU CASES
VS STANDARD-DOSE VACCINES IN ADULTS AGED 50-64[11]

Primary endpoint: rVE against PCR-confirmed influenza compared with standard-dose flu vaccines; 559 patients (2.00 cases per 1000) had PCR-confirmed influenza in the Flublok cohort (N=279,400) vs 925 patients (2.34 cases per 1000) with standard-dose vaccines (N=395,852).

STUDY LIMITATIONS[11]

- Data were limited to 2 influenza seasons; rVE may vary across seasons depending on the vaccine match with circulating strains
- Primary outcome did not include infections in persons who did not undergo PCR testing, which limits generalizability
- Although KPNC has a diverse population, it may not be representative of other populations in the US
- Compliance with the weekly assigned vaccine schedule varied from time to time due to logistical constraints
- The study had limited power to detect a clinically meaningful benefit of Flublok vs standard-dose vaccines with respect to several less frequent outcomes, such as hospitalized, PCR-confirmed influenza

FLU VACCINES TYPICALLY PREVENT 40%-60% OF FLU CASES IN MATCHED FLU SEASONS.
COULD THE EXTRA PROTECTION OF FLUBLOK BENEFIT YOUR PATIENTS?[11]

IMPORTANT SAFETY INFORMATION

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

Please see additional Important Safety Information throughout.

Before administration, please see full Prescribing Information.

Flublok®
Influenza Vaccine

REAL-WORLD EVIDENCE

FLUBLOK WAS ASSOCIATED WITH FEWER FLU HOSPITALIZATIONS VS CELL- AND EGG-BASED STANDARD-DOSE VACCINE COMPARATORS[4]

STUDY DESIGN

- Retrospective test-negative case-control study in approximately 15,000 patients aged 18+ during the 2018-2019 and 2019-2020 flu seasons to investigate the rVE of Flublok vs standard-dose vaccines against influenza hospitalization[4]*
- In the primary analysis, Flublok was evaluated against standard-dose flu vaccines, including[4,16]:
  - **Cell-based: Flucelvax**
  - **Egg-based: Fluarix, Afluria, FluLaval, and Fluzone**

*Flublok (quadrivalent) was evaluated against quadrivalent standard-dose vaccines. The efficacy of Flublok (quadrivalent formulation) is relevant to Flublok (trivalent formulation) because both vaccines are manufactured using the same process and have overlapping compositions.[1,4]

rVE OF FLUBLOK VS STANDARD-DOSE VACCINES AGAINST INFLUENZA HOSPITALIZATION ADJUSTED FOR PROPENSITY SCORES WITH IPWs[4]:

31%
(95% CI: 11, 46)

FEWER FLU HOSPITALIZATIONS WITH FLUBLOK VS STANDARD-DOSE VACCINES IN ~15,000 PATIENTS AGED 18+ ACROSS MULTIPLE FLU SEASONS

Secondary endpoints: When adjusted for propensity scores with inverse probability weights (IPWs)[4]:

- **Flublok was associated with providing greater protection against influenza hospitalization vs standard-dose vaccines for the following populations[4]:**
  - Female sex: **37% rVE (95% CI: 13, 54)**
  - Age 18-64 years: **28% rVE (95% CI: 3, 46)**
  - No high-risk condition: **60% rVE (95% CI: 29, 78)**

IMPORTANT SAFETY INFORMATION

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.

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Flublok®
Influenza Vaccine

REAL-WORLD EVIDENCE

FLUBLOK WAS ASSOCIATED WITH FEWER FLU HOSPITALIZATIONS VS CELL- AND EGG-BASED STANDARD-DOSE VACCINE COMPARATORS[4] (CONT'D)

- Flublok was associated with providing greater (non–statistically significant) protection against influenza hospitalization vs standard-dose vaccines for the following populations[4]:
  - Male sex: 23% rVE (95% CI: -14, 48)
  - Age ≥65 years: 17% rVE (95% CI: -36, 48)
  - High-risk condition: 20% rVE (95% CI: -7, 40)

STUDY STRENGTHS AND LIMITATIONS[4]

- The demographics of the study population were representative of the adult population of Allegheny County (which was 79% white and 51% female), which contributes to generalizability
- The University of Pittsburgh Medical Center hospitals in central and southwestern Pennsylvania are part of an integrated health system, with regular uploads of vaccination data from the state immunization registry; vaccination status was verified through the state registry with a specific data request
- Although the electronic medical record (EMR) system of University of Pittsburgh Medical Center hospitals in central and southwestern Pennsylvania is robust, if vaccinations were not captured in the EMRs or state registry, they were classified as unvaccinated
- Because data focused on hospitalizations, there may have been milder cases of influenza that were not captured in the EMRs because they didn't require medical care
- There is a possibility of selection bias among those who received influenza testing; for instance, clinicians might have preferentially tested unvaccinated subjects, which would increase the proportion of unvaccinated cases
- While a relatively large cohort of adults is included in this study, the sample size of standard-dose flu vaccine recipients may have been inadequate to detect meaningful rVE estimates for specific subgroups

IMPORTANT SAFETY INFORMATION

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.

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Flublok®
Influenza Vaccine

REAL-WORLD SAFETY EVIDENCE

SAFETY PROFILE SUPPORTED IN ONE OF THE LARGEST SAFETY STUDIES OF A FLU VACCINE IN PREGNANT WOMEN, WITH ~15,000 PATIENTS[1,17,18]

STUDY DESIGN

- This was an observational, retrospective safety surveillance study of Flublok Quadrivalent in 14,981 pregnant individuals across Northern Hemisphere influenza seasons 2018-2019 and 2019-2020[1*‡‡]
- This study represents one of the largest populations of pregnant people to be included in the prescribing information for any FDA-approved flu vaccine[1,17,18]

FLUBLOK DEMONSTRATED **NO INCREASED RISK** OF MAJOR BIRTH DEFECTS AND MISCARRIAGES[1†]



THESE DATA SUPPORT THE SAFETY PROFILE OF FLUBLOK

*5842 patients, including those with chronic conditions, were exposed to Flublok Quadrivalent during the 28 days prior to conception or during the first trimester. Miscarriage was reported in 464 (3.1%) patients. Among individuals exposed to Flublok Quadrivalent at any time during pregnancy, 1113 pregnancies (7.7%) had infants with major birth defects (56, 360, 381, and 316 among individuals exposed during the 28 days prior to conception, the first trimester, the second trimester, and the third trimester, respectively).[1]

†Prespecified outcomes included spontaneous abortion and congenital/fetal anomalies. Data were not collected on ectopic pregnancy or elective terminations.[1]

‡The data for Flublok (quadrivalent) are relevant to Flublok (trivalent) because both vaccines were manufactured using the same process and have overlapping compositions.[1]

THE CDC RECOMMENDS FLU VACCINATION FOR PREGNANT PEOPLE TO HELP PROTECT THEM AND THEIR BABIES[19]

- Pregnant people are at higher risk of severe flu-related illness and hospitalization[3]
- Pregnant people who receive a flu vaccination:
  - Have **40% lower risk** of hospitalization with flu[20§]
  - **Help protect their babies from flu-related illness and hospitalization** when they are too young to be vaccinated[19]

§Retrospective test negative design study, 2010-2016, which evaluated adjusted overall influenza vaccine efficacy against influenza-associated hospitalization during pregnancy (N=1030).[20]

IMPORTANT SAFETY INFORMATION

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.

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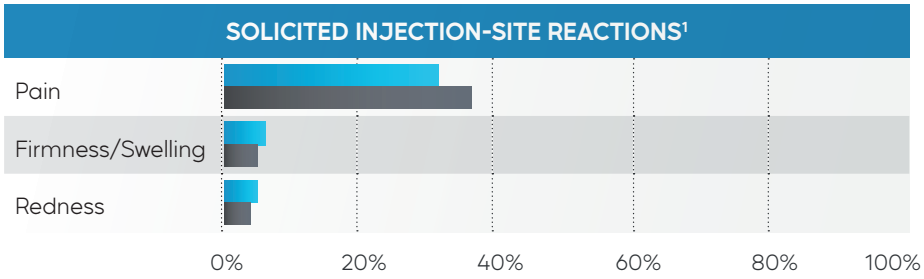
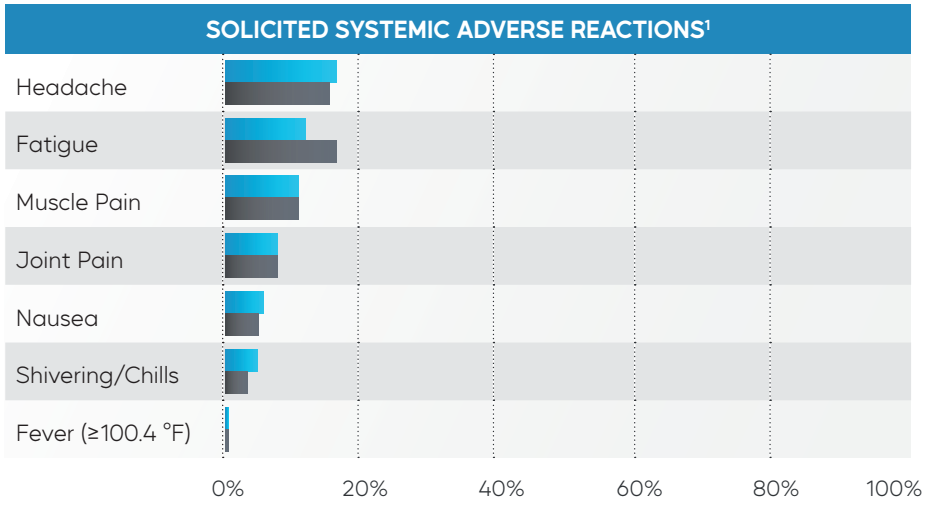
Flublok®
Influenza Vaccine

SIMILAR SAFETY PROFILE COMPARED TO STANDARD-DOSE FLU VACCINES[1]

SAFETY IN ADULTS AGED 50-64[1]

- Rates of local and systemic adverse reactions were similar within 7 days of Flublok (trivalent) or standard-dose influenza vaccine administration
- Pooled data from 2 studies; comparators were Fluzone (trivalent standard-dose formulation) and Afluria (trivalent standard-dose formulation)



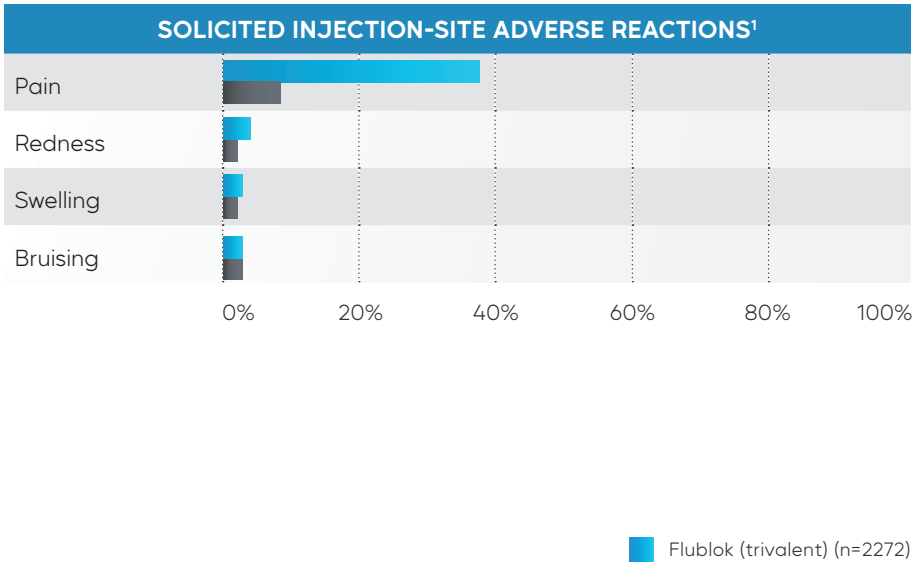


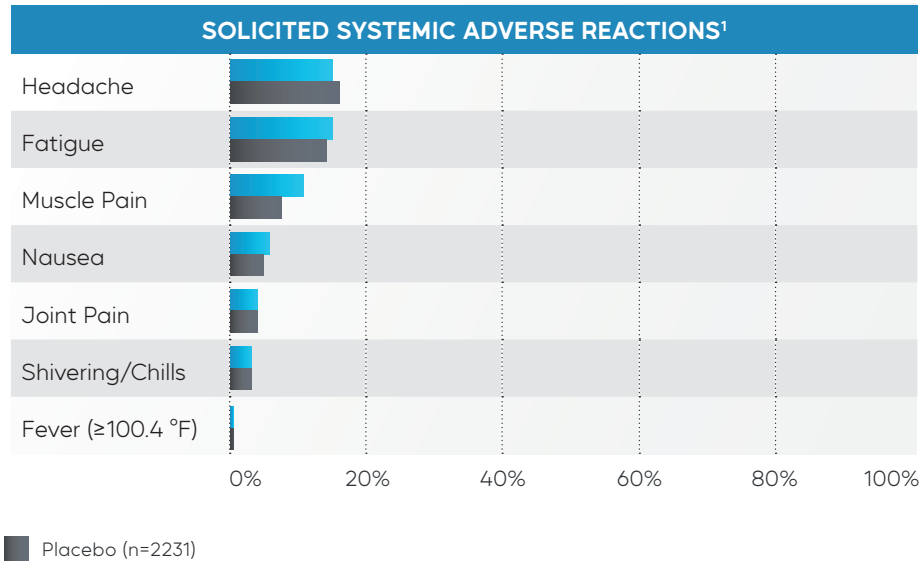
Flublok®
Influenza Vaccine

SAFETY PROFILE IN ADULTS AGED 18-49 COMPARED TO PLACEBO[5]

SAFETY IN ADULTS AGED 18-49[5]

- Safety data from a study of 4648 adults randomized to receive Flublok (trivalent; n=2344) or placebo (n=2304)
- Systemic symptoms following vaccination were similar between people receiving Flublok and placebo
- 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)
  - 76% of headache complaints were mild
- Flublok was associated with local injection-site pain (37% with Flublok vs 8% with placebo) that was significantly more frequent than after saline placebo[1,5]
  - 94% of all pain complaints after Flublok were rated as mild[5]





Flublok (trivalent) (n=2272) Placebo (n=2231)

Flublok®
Influenza Vaccine

IMPORTANT SAFETY INFORMATION & 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.

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Please see the full Prescribing Information.

Flublok®
Influenza Vaccine



HIGHER-DOSE PROTECTION WITH FLUBLOK: PROVEN TO HELP PREVENT FLU AND SHOWN TO REDUCE ITS COMPLICATIONS[1,2*]

FOR PATIENTS 9 YEARS & OLDER[1]

- **3X** Only Flublok has recombinant technology that **eliminates risk of antigenic mismatch** during manufacturing, plus **3x the antigen** of standard-dose vaccines[1-3,6,7†]
- **RCT** Proven to **prevent more flu cases than a standard-dose vaccine** in a randomized controlled trial of adults aged 50+[1,2]
- Evaluated in the **largest real-world flu effectiveness study** to date[11,12]
- **RWE** **Real-world evidence in flu hospitalizations** vs standard-dose vaccines in patients aged 18+[4]
- **Established safety profile[1,5]**
  - Similar safety profile compared with a standard-dose flu vaccine in adults aged 50-64[1,2]
  - Outcomes from one of the largest safety studies of a flu vaccine in pregnant women, which included ~15,000 participants, support the safety profile of Flublok[1,17,18]

*Flublok (quadrivalent) was proven to prevent 30% more flu cases in older adults than Fluarix (quadrivalent standard-dose vaccine) in a phase 3-4 randomized controlled trial of adults aged 50+ (N≈9000) during the 2014-2015 season. The primary endpoint was relative vaccine efficacy against influenza due to any PCR-confirmed circulating strains. The efficacy of Flublok (quadrivalent) is relevant to Flublok (trivalent) because both vaccines are manufactured using the same process and have overlapping compositions.[1]

†Flublok contains 45 mcg of hemagglutinin (HA) per strain compared with 15 mcg of HA in a standard-dose flu vaccine.[1-3]

IMPORTANT SAFETY INFORMATION

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Please see additional Important Safety Information throughout. Before administration, please see full Prescribing Information.

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