

## **FLUZONE® QUADRIVALENT (INFLUENZA VACCINE)**

Fluzone Quadrivalent is a vaccine indicated for active immunization for the prevention of influenza disease caused by influenza A subtype viruses and type B viruses contained in the vaccine. Fluzone Quadrivalent is approved for use in persons 6 months of age and older.

### **IMPORTANT SAFETY INFORMATION FOR FLUZONE® QUADRIVALENT (INFLUENZA VACCINE)**

Fluzone Quadrivalent should not be administered to anyone who has had a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine, including egg protein, or after previous dose of any influenza vaccine.

Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.

If Guillain-Barré syndrome has occurred within 6 weeks following previous influenza vaccination, the decision to give Fluzone Quadrivalent should be based on careful consideration of the potential benefits and risks.

If Fluzone Quadrivalent is administered to immunocompromised persons, including those receiving immunosuppressive therapy, the immune response may be lower than expected.

Vaccination with Fluzone Quadrivalent may not protect all recipients.

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

For Fluzone Quadrivalent, in children 6 months through 35 months of age, the most common injection-site reactions were pain or tenderness, erythema, and swelling; the most common solicited systemic adverse reactions were irritability, abnormal crying, malaise, drowsiness, appetite loss, myalgia, vomiting, and fever. In children 3 years through 8 years of age, the most common injection-site reactions were pain, erythema, and swelling; the most common solicited systemic adverse reactions were myalgia, malaise, and headache. In adults 18 years and older, the most common injection-site reaction was pain; the most common solicited systemic adverse reactions were myalgia, headache, and malaise. Other reactions may occur.

Please see full [Prescribing Information](#) for Fluzone Quadrivalent