

January 2019

Dear Customer:

We are pleased to inform you that Fluzone Quadrivalent vaccine 0.5mL dose is newly approved to be used in children 6 months of age and older, effective January 23, 2019. This new option offers health care providers the simplicity of using the same 0.5mL dose for all eligible children when immunizing against the flu.

Additional important information is provided below:

- Fluzone Quadrivalent 0.5mL dose is currently available to reserve for the 2019-2020 influenza season.
- This approval is supported by clinical data from a Phase IV safety and immunogenicity study conducted in nearly 2,000 children, which demonstrated that one or two doses of 0.5 mL of vaccine in children 6 through 35 months of age had a safety profile that was comparable to one or two doses of 0.25 mL of vaccine with no new safety concerns observed, and induced a robust immune response.
- Fluzone Quadrivalent 0.25mL dose will still be available to order for children ages 6-35 months for the 2019-2020 season.
- CPT codes and payer coverage will not be affected by this new approval.

Sanofi Pasteur's flu vaccine portfolio includes options to help protect all eligible patients from influenza. In addition to Fluzone Quadrivalent vaccine, the product portfolio includes Flublok<sup>®</sup> Quadrivalent (Influenza Vaccine) and Fluzone<sup>®</sup> High-Dose (Influenza Vaccine), the only two flu vaccines proven to help prevent more cases of flu in older adults, compared to their standard-dose flu vaccine comparators in randomized controlled trials.

In randomized controlled trials, the most common local and systemic adverse reactions to Flublok Quadrivalent and Fluzone High-Dose vaccines include pain at the injection site, headache and myalgia.

## **INDICATION FOR FLUBLOK QUADRIVALENT, FLUZONE QUADRIVALENT, AND FLUZONE HIGH-DOSE VACCINES**

Flublok Quadrivalent, Fluzone Quadrivalent, and Fluzone High-Dose vaccines are indicated for active immunization for the prevention of influenza disease caused by influenza A subtype viruses and type B virus(es) contained in each vaccine. Flublok Quadrivalent vaccine is approved for use in persons 18 years of age and older. Fluzone Quadrivalent vaccine is approved for use in persons 6 months of age and older. Fluzone High-Dose vaccine is approved for use in persons 65 years of age and older.

## **IMPORTANT SAFETY INFORMATION FOR FLUBLOK QUADRIVALENT, FLUZONE QUADRIVALENT, AND FLUZONE HIGH-DOSE VACCINES**

Flublok Quadrivalent, Fluzone Quadrivalent, and Fluzone High-Dose vaccines should not be administered to anyone who has had a severe allergic reaction (eg, anaphylaxis) to any component of the vaccine (including egg protein for Fluzone Quadrivalent and Fluzone High-Dose vaccines) after a previous dose of the respective vaccine. In addition, Fluzone Quadrivalent and Fluzone High-Dose vaccines should not be administered to anyone who has had a severe allergic reaction after a previous dose of any influenza vaccine.

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

In adults, the most common local and systemic adverse reactions to Flublok Quadrivalent, Fluzone Quadrivalent, and Fluzone High-Dose vaccines include pain at the injection site; headache and myalgia. In children, the most common reactions to Fluzone Quadrivalent vaccine include pain, erythema, and swelling at the injection site; myalgia, malaise, and headache (irritability, abnormal crying, drowsiness, appetite loss, vomiting, and fever in young children). Other adverse reactions to these vaccines may occur. Vaccination with Flublok Quadrivalent, Fluzone Quadrivalent, or Fluzone High-Dose vaccine may not protect all individuals.

Before administering [Flublok Quadrivalent](#), [Fluzone Quadrivalent](#), or [Fluzone High-Dose](#) vaccine, please see accompanying full Prescribing Information.

Should you have any additional questions, please contact Sanofi Pasteur at 1-800-VACCINE (1-800-822-2463).

Regards,



Jennifer Havens  
Head of Fluzone Quadrivalent Marketing

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