

Quadrivalent Influenza Vaccine Types A and B Subvirion (FluQuadri®) Abridged Product Information 2023 Flu Season

Quadrivalent Influenza Vaccine (Types A and B Subvirion)



Product: Quadrivalent Influenza Vaccine Types A and B Subvirion (FluQuadri®)

Strength: 0.5 mL Suspension for Injection for Intramuscular Injection in prefilled syringe

Presentation: 0.5 mL Type 1 single dose prefilled syringe (clear plunger rod), without needle (Box of 5)

I: *Quadrivalent Influenza Vaccine For the prevention of influenza disease caused by influenza types A and B viruses contained in the vaccine. It is administered intramuscularly in persons 6 months of age and older.*

C: Hypersensitivity to the active substances or to any of the excipients listed including egg protein, or to a previous dose of any influenza vaccine.

W/P: Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine. If Quadrivalent Influenza Vaccine Types A and B Subvirion (FluQuadri®) is administered to immunocompromised persons, including those receiving immunosuppressive therapy, the expected immune response may not be obtained. Recurrence of Guillain Barré syndrome (GBS) has been temporally associated with administration of influenza vaccine. If GBS has occurred within 6 weeks of previous influenza vaccination, the decision to give Quadrivalent Influenza Vaccine Types A and B Subvirion (FluQuadri®) should be based on careful consideration of the potential benefits and risks. Vaccination with Quadrivalent Influenza Vaccine Types A and B Subvirion (FluQuadri®) may not protect all recipients. Inspect Quadrivalent Influenza Vaccine Types A and B Subvirion (FluQuadri®) visually for particulate matter and/or discoloration prior to administration. If either of these conditions exist, the vaccine should not be administered.

Interactions: Quadrivalent Influenza Vaccine Types A and B Subvirion (FluQuadri®) vaccine should not be combined through reconstitution or mixed with any other vaccine. Data evaluating the concomitant administration of Quadrivalent Influenza Vaccine Types A and B Subvirion (FluQuadri®) with other vaccines are not available.

AE: Tenderness or pain at the injection site, headache, myalgia, malaise, fever, irritability, drowsiness, appetite loss, vomiting

PK/ PD: Quadrivalent Influenza Vaccine Types A and B Subvirion (FluQuadri®) for intramuscular injection is an inactivated influenza vaccine, prepared from influenza viruses propagated in embryonated chicken eggs. The virus containing allantoic fluid is harvested and inactivated with formaldehyde. Influenza virus is concentrated and purified in a linear sucrose density gradient solution using a continuous flow centrifuge. The Quadrivalent Influenza Vaccine Types A and B Subvirion (FluQuadri®) process uses an additional concentration factor after the ultrafiltration step in order to obtain a higher hemagglutinin (HA) antigen concentration. Antigens from the four strains included in the vaccine are produced separately and then combined to make the quadrivalent formulation. Frequent development of antigenic variants through antigenic drift is the virologic basis for seasonal epidemics and the reason for the usual change of one or more new strains in each year's influenza vaccine. Therefore, influenza vaccines are standardized to contain the hemagglutinins of influenza virus strains representing the influenza viruses likely to be circulating in the next season. Annual vaccination with the current vaccine is recommended because immunity during the year after vaccination declines and because circulating strains of influenza virus change from year to year. In a multi center study conducted in the US, children 6 months through 8 years of age, adults greater than or equal to 18 years of age, and geriatric adults greater than or equal to 65 years of age were included in the per protocol immunogenicity analysis.

Date of Revision: December 2022

Reference: 2023 Quadrivalent Influenza Vaccine Types A and B Subvirion (FluQuadri®). Philippines Prescribing Information.

Sanofi Pasteur Inc.

21st & 22nd Floors, One World Place Corporate Offices,
32nd Street, Bonifacio Global City, Taguig City, Metro Manila
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