Prescribing Information: Quadrivalent Influenza Vaccine (split virion, inactivated) suspension for injection in pre-filled syringe

Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

Presentation: Available as single dose pre-filled syringes containing 0.5 mL of suspension for injection. Quadrivalent Influenza Vaccine (split virion, inactivated) contains 15 µg of antigen (per 0.5 mL) from each of the four virus strains recommended by the World Health Organization for the present influenza season.

Indication: The prevention of influenza disease caused by the two influenza A virus subtypes and the two influenza B virus types contained in the vaccine for active immunisation of adults, including pregnant women, and children from 6 months of age and older, and for passive protection of infants from birth to less than 6 months of age following vaccination of pregnant women. The use of Quadrivalent Influenza Vaccine (split virion, inactivated) should be based on official recommendations.

Dosage and Administration: One 0.5 mL dose every year should be given by intramuscular (IM) or subcutaneous injection into the deltoid muscle. Under no circumstances should this vaccine be administered intravascularly.

Special Populations: Paediatric population: Children 6 months of age and older should receive on 0.5 mL dose every year. The preferred sites for IM injection are the anterolateral aspect of the thigh (or the deltoid muscle if muscle mass is adequate) in children 6 months to 35 months of age, or the deltoid muscle in children from 36 months of age. Children aged less than 9 years who have not been previously vaccinated should receive a second dose of vaccine after an interval of at least 4 weeks. The safety and efficacy of administration (active immunisation) in infants less than 6 months have not been established. Regarding passive protection, one 0.5 mL dose given to pregnant women may protect infants from birth to less than 6 months of age, however not all of these infants will be protected.

Contraindications: Hypersensitivity to the active substances, to any of the excipients or to any component that may be present as traces from the manufacturing process such as eggs (ovalbumin, chicken proteins), neomycin, formaldehyde and octoxinol-9. Vaccination should be postponed in case of moderate or severe febrile disease or acute disease.

Warnings and precautions: Quadrivalent Influenza Vaccine (split virion, inactivated) is intended to provide protection against those strains of influenza virus from which the vaccine is prepared. As with any vaccine, vaccination with Quadrivalent Influenza Vaccine (split virion, inactivated) may not protect all vaccinees. Regarding passive protection, not all infants less than 6 months of age born to women vaccinated during pregnancy will be protected. Prior to immunisation: Appropriate medical treatment and supervision should always be readily available in the event of an anaphylactic reaction. Administration precautions: The vaccine should be administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to these subjects. Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. Procedures should be in place to prevent injury from fainting and manage syncopal reactions. Antibody response in patients with endogenous or iatrogenic immunosuppression may be insufficient. Excipients of known effect: It contains less than 1 mmol potassium (39 mg) and less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'potassium-free' and 'sodium-free'.

Interactions: Other vaccines may be given at the same time at separate injection sites and using separate syringes. The immunological response may be reduced if the patient is undergoing immunosuppressant treatment. Following influenza vaccination, false positive results in serology tests using the ELISA method to detect antibodies against HIV1, Hepatitis C and especially HTLV1 have been observed. The Western Blot technique disproves the false-positive ELISA test results. The transient false positive reactions could be due to the IgM response by the vaccine.

Fertility, pregnancy and lactation: Quadrivalent Influenza Vaccine (split virion, inactivated) can be used in all stages of pregnancy. Larger datasets on safety of inactivated influenza vaccines are available for the second and third trimesters than for the first trimester. Data from worldwide use of inactivated influenza vaccines do not indicate any adverse fetal and maternal outcomes attributable to the vaccine. Quadrivalent Influenza Vaccine (split virion, inactivated) may be administered during breast-feeding.

Adverse reactions: Very common: *Adults:* headache, myalgia, malaise, injection site pain. *Paediatric population (children 3 – 17 years of age):* headache, myalgia, malaise, shivering, injection site reactions (pain, swelling, erythema, induration). *Paediatric population (children 3 months to 36 months of age):* headache, vomiting, myalgia, irritability, appetite loss, abnormal crying, malaise, fever, drowsiness, injection site reactions (pain, tenderness, erythema). Common: *Adults:* shivering, fever, injection site reactions (erythema, swelling, induration). *Paediatric population (children 3 – 17 years of age):* fever, and injection site ecchymosis. *Paediatric population (children 3 months to 36 months of age):* shivering and injection site reactions (induration, swelling and ecchymosis). Other Serious Adverse Drug Reactions: *Adults (Uncommon)*: Lymphadenopathy. *Paediatric population (children 3 – 17 years of age) (Uncommon):* Thrombocytopenia. *Adults (Rare):* Paraesthesia. *Adults and paediatric population (frequency not known):* anaphylactic/allergic reactions. The following adverse events were reported following commercial use of Inactivated Influenza Vaccine (Split Virion) BP: Vasculitis (such as Henoch-Schonlein purpura) and transient thrombocytopenia and lymphadenopathy as well as neurological disorders such as encephalomyelitis, neuritis, neuralgia, convulsions, and Guillain-Barré syndrome. A causal relationship with Quadrivalent Influenza Vaccine (split virion, inactivated) has not been established. *Prescribers should consult the SmPC in relation to other adverse reactions.*

List Price: Single dose pre-filled syringes in single packs: £8.00; Packs of 10 single dose prefilled syringes: £80.00.

Legal Category: POM.

Marketing Authorisation Number: PL 23228/0010

Marketing Authorisation Holder: Sanofi Winthrop Industrie, 82 avenue Raspail, 94250 Gentilly, France.
Further information is available from: Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK. uk-medicalinformation@sanofi.com

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Adverse events should also be reported to the Sanofi drug safety department on Tel: 0800 0902 314. Alternatively, send via email to UK-drugsafety@sanofi.com