Prescribing Information:

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

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

Presentation: Quadrivalent Influenza Vaccine (split virion, inactivated) contains 15 micrograms of antigen (per 0.5 millilitre) from each of the four virus strains recommended by the World Health Organization for the present influenza season. It is supplied as single dose prefilled syringes each containing 0.5 millilitre of suspension for injection. The vaccine may contain traces of eggs, such as ovalbumin, neomycin, formaldehyde and octoxinol-9 which are used during the manufacturing process.

Indication: Quadrivalent Influenza Vaccine (split virion, inactivated) is indicated for 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: Adults and children from 6 months should receive one 0.5 millilitre dose every year. 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 Quadrivalent Influenza Vaccine (split virion, inactivated) administration (active immunisation) in infants less than 6 months have not been established. Regarding passive protection, one 0.5ml 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. Doses should be given by intramuscular or subcutaneous injection. The preferred sites for intramuscular 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 and adults.

Contraindications: Hypersensitivity to the active substances, to any of the excipients listed in section 6.1 of the Summary of Product Characteristics or to any component that may be present as traces 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: In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded. Do not administer intravascularly. Medical treatment and supervision should always be available in the event of an anaphylactic reaction following administration of the vaccine. Immunosuppressed (endogenous or iatrogenic) subjects may not produce adequate antibodies. 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. Other vaccines may be given at the same time at separate injection sites. 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'. 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.

Pregnancy and breastfeeding: 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; however, data from worldwide use of inactivated influenza vaccines do not indicate any adverse foetal and maternal outcomes attributable to the vaccine. Quadrivalent Influenza Vaccine (split virion, inactivated) may be administered during breastfeeding.

Adverse reactions: Adults and the elderly; Very common (≥1/10): headache, myalgia, malaise, injection site pain. Common (≥1/100 to <1/10): shivering, fever, injection site reactions (erythema, swelling, and induration). Uncommon (≥1/1,000 to <1/100): Lymphadenopathy Rare (≥1/10,000 to <1/1,000): Paraesthesia.

Children 3 to 17 years of age; Very common (≥1/10): headache, myalgia, malaise, shivering, injection site reactions (pain, swelling, erythema and induration). Common (≥1/100 to <1/10): fever, and injection site ecchymosis. Uncommon (≥1/1,000 to <1/100): Thrombocytopenia.

Children 6 to 35 months of age; Very common (≥1/10): headache, vomiting, myalgia, irritability, appetite loss, abnormal crying, malaise, fever, drowsiness and injection site reactions (pain, tenderness and erythema). Common (≥1/100 to <1/10): shivering and injection site reactions (induration, swelling and ecchymosis).

The following adverse events were reported following commercial use of Inactivated Influenza Vaccine (Split Virion) BP. A causal relationship with Quadrivalent Influenza Vaccine (split virion, inactivated) has not been established. 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.

For a complete list of undesirable effects please refer to the Summary of Product Characteristics.

Package quantities and basic NHS cost: Single dose prefilled syringes in single packs, basic NHS cost £8.00; packs of 10 single dose prefilled syringes, basic NHS cost £80.00.

Legal Category: POM

Marketing Authorisation Number: PL 46602/0017

Marketing Authorisation Holder: Sanofi Pasteur Europe, 14 Espace Henry Vallée, 69007 Lyon, France

Further information is available from: Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT
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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