Prescribing Information: Supemtek▼solution for injection in pre-filled syringe. Quadrivalent Influenza Vaccine (recombinant, prepared in cell culture)

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

Presentation: Quadrivalent Influenza Vaccine (recombinant, prepared in cell culture) contains 45 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.

Indication: Supemtek is indicated for active immunisation for the prevention of influenza disease in adults. Supemtek should be used in accordance with official recommendations.

Dosage and Administration: One dose of 0.5 mL given intramuscularly. The preferred site is in the deltoid muscle. The vaccine must not be injected intravascularly and must not be mixed with other vaccines in the same syringe. *Paediatric population:* Safety and efficacy of Supemtek have not yet been established in individuals below 18 years of age.

Contraindications: Hypersensitivity to the active substances, to any of the excipients or to any trace residuals such as octylphenol ethoxylate.

Precautions and Warnings: Hypersensitivity: Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine. Intercurrent illness: Vaccination should be postponed in patients with acute febrile illness until the fever is resolved. Immunodeficiency: Antibody response in patients with endogenous or iatrogenic immunosuppression may be insufficient to prevent influenza. Thrombocytopenia and coagulation disorders: As with all injectable vaccines, Supemtek must be administered with caution to individuals with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to these subjects. Syncope: Syncope can occur following or even before any vaccination as a psychogenic response to the needle injection. This can be accompanied by several neurological signs. Protection: As with any vaccine, vaccination with Supemtek may not protect all vaccinees. Sodium content: This medicinal product contains less than 1 mmol sodium (23 mg) per dose, that is to say is essentially “sodium free”.

Interactions: No interaction studies have been performed, nor data to assess the concomitant administration of Supemtek with other vaccines. If Supemtek is to be given at the same time as another injectable vaccine, the vaccines should always be administered at different injection sites.

Pregnancy: There is a limited amount of data from the use of Supemtek in pregnant women. One animal study performed with trivalent recombinant influenza vaccine did not indicate direct or indirect harmful effects with respect to pregnancy, embryo-foetal development or early post-natal development. An assessment of the risks and benefits should be performed by a healthcare professional before administering Supemtek to a pregnant woman. Breast-feeding: It is not known whether Supemtek vaccine is excreted in human milk. An assessment of the risks and benefits should be performed by a healthcare professional before administering Supemtek to a breast-feeding woman. Fertility: No human fertility data are available. The animal study with trivalent recombinant influenza vaccine did not indicate harmful effects on female fertility.

Adverse Reactions: *Very common (≥1/10)*: Headache, fatigue, myalgia, arthralgia, local tenderness, local pain. *Common (≥1/100 to <1/10)*: Nausea, firmness / swelling, redness, fever, shivering / chills. **Prescribers should consult the SmPC in relation to other adverse reactions.**

List price: Packs of 10 single dose pre-filled syringes, basic NHS cost £175.50

Legal Category: POM

Marketing Authorisation Number: PLGB 04425/0879

Marketing Authorisation Holder: Aventis Pharma Ltd, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK (trading as Sanofi Pasteur) 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