

Prescribing Information: Supemtek TIVr Trivalent Influenza Vaccine (recombinant, prepared in cell culture), solution 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 each containing 0.5 mL of solution for injection. Trivalent Influenza Vaccine (recombinant, prepared in cell culture) contains 45 micrograms of antigen (per 0.5 mL) from each of the three virus strains recommended by the World Health Organization (WHO) for the present influenza season.

Indication: Active immunisation for the prevention of influenza disease in adults and children from 9 years of age and older. Supemtek TIVr 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.

Special populations: Paediatric population: Safety and efficacy of Supemtek TIVr have not been established in individuals below 3 years of age.

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

Warnings and Precautions: As with any vaccine, vaccination with Supemtek TIVr may not protect all vaccinees. Prior to immunisation: Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine. Vaccination should be postponed in patients with acute febrile illness until the fever is resolved. Antibody response in patients with endogenous or iatrogenic immunosuppression may be insufficient to prevent influenza. Administration precautions: As with all injectable vaccines, Supemtek TIVr 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 (fainting) can occur following or even before any vaccination as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. Procedures should be in place to prevent falling and injury and to manage syncope. Excipients of known effect: This medicinal product contains less than 1 mmol sodium (23 mg) per

dose, that is to say is essentially “sodium free”. This medicine contains 0.0275 mg of polysorbate 20 (E432) in each 0.5 mL dose. Polysorbates may cause allergic reactions.

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

Fertility, pregnancy and lactation: A large amount of data on pregnant women (more than 14,500 pregnancy outcomes from a retrospective study), indicates no malformative nor foeto/neonatal toxicity of Quadrivalent Influenza Vaccine (recombinant, prepared in cell culture) (Supemtek) when administered during pregnancy. Supemtek TIVr can be used during pregnancy in accordance with official recommendations. It is not known whether Supemtek TIVr vaccine is excreted in human milk. An assessment of the risks and benefits should be performed by a health care professional before administering Supemtek TIVr to a breastfeeding woman. No human fertility data are available.

Adverse Reactions: Very common: Headache, malaise, fatigue, myalgia, arthralgia, local tenderness, local pain/injection site pain. Common: nausea, fever, shivering/chills, firmness/swelling, redness/injection site erythema, bruising, induration. Other Serious Adverse Reactions (frequency not known): Guillain-Barré Syndrome, Hypersensitivity including anaphylactic reaction. The safety profile of Supemtek TIVr is comparable with that of quadrivalent recombinant influenza vaccine. *Prescribers should consult the SmPC in relation to other adverse reactions.*

List price: Packs of 10 single dose pre-filled syringes without needles: £175.50

Legal Category: POM

Marketing Authorisation Number: PLGB 04425/0909

Marketing Authorisation Holder: Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK

Further information is available from: Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK. uk-medicalinformation@sanofi.com.

Date of preparation: February 2026

Document Number: MAT-XU-2404767 (v2.0)

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