

Prescribing Information: Vaxigrip Trivalent 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. Vaxigrip (split virion, inactivated) contains 15 µg of antigen (per 0.5 mL) from each of the three virus strains recommended by the World Health Organization for the present influenza season. The vaccine, after shaking gently, is a colourless opalescent liquid.

Indication: Vaxigrip is indicated for the prevention of influenza disease caused by the two influenza A virus subtypes and influenza B virus type 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 Vaxigrip 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: One dose of 0.5mL for children from 6 months to 17 years 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 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, 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.

Warnings and precautions: Vaxigrip is intended to provide protection against those strains of influenza virus from which the vaccine is prepared. As with any vaccine, vaccination with Vaxigrip 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. Vaccination should be postponed in case of moderate or severe febrile disease or acute disease. **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: Vaxigrip could be given at the same time as other vaccines if needed. Data showing that Vaxigrip can be administered concomitantly with other vaccines are available for the following vaccines: a pneumococcal polysaccharide vaccine, a tetanus, diphtheria, pertussis, polio vaccine (Tdap-IPV, Repevax), and a zoster vaccine. If Vaxigrip is given at the same time as other vaccines, separate injection sites and separate syringes should be used. The immunological response may be reduced if the patient is undergoing immunosuppressant treatment.

Fertility, pregnancy and lactation: Vaxigrip 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 with the first trimester. Data from worldwide use of inactivated influenza vaccines, including Vaxigrip and Quadrivalent Influenza Vaccine (split virion, inactivated), do not indicate any adverse foetal and maternal outcomes attributable to the vaccine. Vaxigrip may be administered during breast-feeding. No fertility data are available in Humans.

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 pain/tenderness, erythema, swelling and induration (3-8 years of age). **Paediatric population (children 24-35 months of age):** headache, myalgia, injection site pain/tenderness and erythema, malaise, fever. **Paediatric population (children 6-23 months of age):** decreased appetite, crying abnormal, irritability, drowsiness, vomiting, injection site pain/tenderness and erythema, fever. **Common: Adults:** shivering, fever, injection site reactions (erythema, swelling, induration). **Paediatric population (children 3 – 17 years of age):** fever, and injection site ecchymosis/induration (9-17 years of age). **Paediatric population (children 6-35 months of age):** diarrhoea, Injection site reactions (induration, swelling, ecchymosis) shivering (24-35 months of age). **Serious Adverse Drug Reactions (frequency not known):** Nervous system disorders including convulsion and Guillain-Barré Syndrome. Vasculitis such as Henoch-Schonlein purpura, with transient renal involvement in certain cases. Hypersensitivity including anaphylactic reaction. *Prescribers should consult the SmPC in relation to other adverse reactions.*

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

Legal Category: POM.

Marketing Authorisation Number: PL 04425/0910

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

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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