

Prescribing Information: Efluelda TIV-HD ▼ 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: Efluelda TIV-HD (split virion, inactivated) contains 60 micrograms of antigen (per 0.5 ml dose) from each of the three virus strains recommended by the World Health Organization for the present influenza season. It is supplied as single dose pre-filled syringe each containing 0.5 ml of suspension for injection. Efluelda TIV-HD after shaking gently, is a colourless opalescent liquid.

Indication: Efluelda TIV-HD is indicated for active immunisation in adults 60 years of age and older for the prevention of influenza disease. The use of Efluelda TIV-HD should be in accordance with official recommendations on vaccination against influenza.

Dosage and Administration: Adults 60 years and older should receive one 0.5 ml dose. *Paediatric population:* The safety and effectiveness of Efluelda TIV-HD, in children less than 18 years of age have not been established. *Method of administration:* The preferred route of administration for this vaccine is intramuscular although it may also be given subcutaneously. The recommended site for intramuscular injection is the deltoid region. The vaccine should not be injected into the gluteal region, or into areas where there may be a major nerve trunk.

Contraindications: Hypersensitivity to the active substances or to any of the excipients listed in SmPC or to any component that may be present as traces such as eggs (ovalbumin, chicken proteins) and formaldehyde.

Warnings and precautions: As with any vaccine, a protective response may not be elicited in all vaccine recipients. 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. Efluelda TIV-HD should under no circumstances be administered intravascularly. Vaccination should be postponed in patients with acute febrile illness until the fever is resolved. Administration precautions: If Guillain-Barré syndrome (GBS) has occurred within 6 weeks of any previous influenza vaccination, the decision to give Efluelda TIV-HD should be based on careful consideration of the potential benefits and risks. As with other vaccines administered intramuscularly, the vaccine should be administered with caution to subjects with thrombocytopaenia 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: This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially "sodium free".

Interactions: If Efluelda TIV-HD needs to be given at the same time as another injectable vaccine(s), immunisation should be carried out on separate limbs. It should be noted that the adverse reactions may be intensified by any co-administration. The immunological response may be reduced if the patient is undergoing immunosuppressant treatment.

Fertility, pregnancy and lactation: Efluelda TIV-HD is only indicated for use in adults aged 60 years and older. Efluelda TIV-HD has not been clinically evaluated in pregnant and breast-feeding women. Please see SmPC for further information.

Adverse Reactions: Very common: Injection site pain, injection site erythema, malaise, myalgia, headache. Common: Injection site swelling, injection site induration, injection site bruising, fever (>37.5°C), shivering. Other Serious Adverse Drug Reactions (frequency not known): Nervous system disorders including Guillain-Barré Syndrome, convulsions, myelitis and facial palsy. Thrombocytopenia and lymphadenopathy. Hypersensitivity including anaphylactic reaction. *Prescribers should consult the SmPC in relation to other adverse reactions.*

List Price: Packs of 10 single dose pre-filled syringes without needles: £220.00

Legal Category: POM

Marketing Authorisation Number: PL 04425/0911
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
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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