Prescribing Information: Quadrivalent Influenza Vaccine ▼ (split virion, inactivated) High-Dose, suspension for injection in pre-filled syringe

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

Presentation: Quadrivalent Influenza Vaccine (split virion, inactivated) High-Dose contains 60 micrograms of antigen (per 0.7 ml dose) 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 syringe each containing 0.7 ml of suspension for injection. The vaccine may contain traces of eggs, such as ovalbumin, formaldehyde which are used during the manufacturing process.

Indication: Quadrivalent Influenza Vaccine (split virion, inactivated) High-Dose is indicated for active immunisation in adults 60 years of age and older for the prevention of influenza disease. The use of Quadrivalent Influenza Vaccine (split virion, inactivated) High-Dose should be in accordance with official recommendations on vaccination against influenza.

Dosage and Administration: Adults 60 years and older should receive one 0.7 ml dose. *Paediatric population:* The safety and effectiveness of Quadrivalent Influenza Vaccine (Split Virion, Inactivated) High-Dose 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 all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic reaction following the administration of the vaccine. Quadrivalent Influenza Vaccine (Split Virion, Inactivated) High-Dose should under no circumstances be administered intravascularly. Vaccination should be postponed in patients with acute febrile illness until the fever is resolved. If Guillain-Barré syndrome (GBS) has occurred within 6 weeks of any previous influenza vaccination, the decision to give Quadrivalent Influenza Vaccine (Split Virion, Inactivated) High-Dose 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. As with any vaccine, a protective response may not be elicited in all vaccine recipients. This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially "sodium free".

Interactions: If Quadrivalent Influenza Vaccine (Split Virion, Inactivated) High-Dose 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: Quadrivalent Influenza Vaccine (Split Virion, Inactivated) High-Dose is only indicated for use in adults aged 60 years and older. Quadrivalent Influenza Vaccine (Split Virion, Inactivated) High-Dose has not been clinically evaluated in pregnant and breast-feeding women. Please see SmPC for further information.

Adverse Reactions: Very common (≥1/10): Injection site pain, injection site erythema, malaise, myalgia, headache. Common (≥1/100 to <1/10): Injection site swelling, injection site induration, injection site bruising, fever (>37.5°C), shivering. Prescribers should consult the SmPC in relation to other adverse reactions.

List Price: Packs of 10 single dose pre-filled syringes, basic NHS cost £240.00

Legal Category: POM

Marketing Authorisation Number: PL 04425/0758

Marketing Authorisation Holder: Aventis Pharma Limited, 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-medicalinformation@sanofi.com.

Date of preparation: June 2024

Document Number: MAT-XU-2402111 (v1.0)

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