Enzira® Suspension for Injection, pre-filled syringe Influenza Vaccine (Split Virion, inactivated)

Influenza vaccine (split virion, inactivated), pre-filled syringe

UK Abbreviated Prescribing Information:

**Presentation:** Each 0.5 ml dose contains 15 micrograms of each of three purified influenza virus antigens prepared from the strains of influenza virus that comply with the WHO recommendations (northern hemisphere) and EU decision for the current season.

**Indications:** Prophylaxis of influenza, especially in those groups who run an increased risk of associated complications. ENZIRA is indicated in adults and children from 5 years of age. The use of ENZIRA should be based on official recommendations.

**Dosage and Administration:** Adults and children from 5 years: 0.5 ml. For children aged less than 9 years, who have not previously been vaccinated, a second dose should be given after an interval of at least 4 weeks. Immunisation should be carried out by intramuscular or deep subcutaneous injection.

**Contra-indications:** Hypersensitivity to the active substances, to any of the excipients or to any component that may be present as traces such as eggs (ovalbumin, chicken proteins), neomycin and polymyxin. Immunisation shall be postponed in patients with febrile illness or acute infection.

**Warnings and Precautions:**

**Paediatric population**
During the 2010 Southern Hemisphere influenza season, there was an unexpected increase in reports of fever and febrile convulsions in children aged less than 5 years following seasonal influenza vaccination with this product. Febrile convulsions were reported uncommonly (i.e. reporting frequency estimated to be in the range ≥1/1000 to < 1/100)*. An increased number of reports of fever was also reported in the age group 5 to less than 9 years. On the basis of the increased risk of febrile convulsions in children less than 5 years of age, the vaccine indication has been restricted to use in adults and children from 5 years of age only.

(*estimated from epidemiological investigations).

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of rare anaphylactic event following administration of the vaccine. ENZIRA®/Influenza Vaccine (Split Virion, inactivated) Ph.Eur should under no circumstances be administered intravascularly. Antibody response in patients with endogenous or iatrogenic immunosuppression may be insufficient.

**Interactions:** ENZIRA®/Influenza Vaccine (Split Virion, inactivated) Ph.Eur may be given at the same time as other vaccines. Immunisation should be carried out on separate limbs. It should be noted that the adverse reactions may be intensified. The immunological response may be diminished if the patient is undergoing immunosuppressant treatment. Following influenza vaccination, false positive results in serological tests using the ELISA method to detect antibodies against HIV1, Hepatitis C and especially HTLV1 have been observed. The Western Blot technique disproves the results. The transient false positive reactions could be due to the IgM response to the vaccine.
Pregnancy and Lactation: Inactivated influenza vaccines can be used in all stages of pregnancy. Larger datasets on safety are available for the second and third trimester, compared with the first trimester; however, data from worldwide use of inactivated influenza vaccines do not indicate any adverse foetal and maternal outcomes attributable to the vaccine. An animal study conducted with ENZIRA did not indicate reproductive toxicity. ENZIRA®/Influenza Vaccine (Split Virion, inactivated) Ph.Eur may be used during breastfeeding.

Side Effects: Adverse reactions observed from clinical trials: Commonly reported are administration site conditions (for example redness, swelling, or pain), ecchymosis, induration, fever, malaise, shivering, fatigue, headache, sweating, myalgia and arthralgia. Adverse reactions from post marketing surveillance: Generalised skin reactions including pruritus, urticaria and non-specific rash. Neuralgia, paraesthesia, convulsions (including febrile convulsions), neurological disorders including encephalomyelitis, neuritis and Guillain-Barré syndrome. Thrombocytopenia and transient lymphadenopathy. Allergic or immediate hypersensitivity reactions including anaphylactic shock and angioedema. Vasculitis associated in very rare cases with transient renal involvement. Localised or diffuse inflammation of connective tissue including large injection site swelling (often reported as cellulitis).

Legal Category: POM.

Package Quantities: Packs of 1 or 10 pre-filled syringes with 25G 5/8" needles

Product Licence Number for ENZIRA and Influenza Vaccine (Split Virion, inactivated) Ph.Eur: PL 22236/0001

Basic NHS Cost for ENZIRA: 0.5ml disposable syringe £5.25, 10 pack £52.50
Basic NHS Cost for Influenza Vaccine (Split Virion, inactivated) Ph.Eur: 0.5ml disposable syringe £6.59, 10 pack £65.90

For full prescribing information and details of other side effects see Summary of Product Characteristics.

Further information is available on request from the Medical Information Department at Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS, UK.

Marketing Authorisation Holder: Seqirus GmbH, Emil-von-Behring-Strasse 76, 35041 Marburg, Germany. Further information is available on request.

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Pfizer Medical Information on 01304 616161

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