INFLUENZA VACCINE
Fluarix®

Fluarix® is an inactivated influenza vaccine (split virion), containing antigens (propagated in embryonated eggs) equivalent to the following types and subtypes:
A/California/7/2009 (H1N1)pdm09-like strain [variant A/Christchurch/16/2010 (NIB-74xp)]
A/Switzerland/9715293/2013 (H3N2)-like strain [variant A/Switzerland/9715293/2013 (NIB-88)]
B/Phuket/3073/2013-like strain [B/Phuket/3073/2013] (Yamagata lineage)

This vaccine complies with the WHO recommended strains (Southern Hemisphere) for the season 2015.

Each 0.5 ml vaccine dose (Fluarix®) contains 15 µg haemagglutinin of each of the recommended strains.

Indication: Fluarix® is a recommended prophylaxis against influenza in adults and children older than 6 months of age

Dosage and Administration:
Fluarix® can be administered intramuscularly or subcutaneously.
Adults and children over 3 years of age: one dose of 0.5ml
Children from 6 to 36 months of age: one dose 0.25 ml or 0.5 ml*
(*Fluarix® should be used in accordance with available official recommendations)

Fluarix® should be administered before the beginning of the influenza season or as required by the epidemiological situation. Vaccination should be repeated every year with an age-appropriate dose of vaccine of updated antigen composition

Contraindications: Fluarix® should not be administered to subjects with known hypersensitivity to the active substances, to any excipients, to egg, to chicken protein, formaldehyde, gentamycin or sodium deoxycholate.

Warnings and Precautions: As with other vaccines, administration of Fluarix® should be postponed in subjects suffering from acute severe febrile illness. The presence of minor illness with or without fever should not contra-indicate the use of Fluarix®.
Fluarix® will only prevent disease caused by influenza viruses. Infections with other agents causing flu-like symptoms are not prevented by the vaccine. Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine.
Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. It is important that procedures are in place to avoid injury from faints.

Interactions: Immunisation can be affected by concomitant immunosuppressive therapy or an existing immunodeficiency.
Fluarix® can be administered simultaneously with other vaccines. However, different injection sites must be selected.

Pregnancy and Lactation: The safety of Fluarix® when administered to pregnant women has not been evaluated. Fluarix® should be used during pregnancy only when clearly needed, and the possible advantages outweigh the potential risks for the fetus.
The safety of Fluarix® when administered to breastfeeding women has not been evaluated.

Adverse Reactions:
Very common: pain at the injection site, appetite loss, irritability, drowsiness, headache, fatigue, myalgia
Common: redness, swelling and induration at the injection site, sweating, shivering, arthralgia
Uncommon: dizziness, fever

Post-marketing surveillance
Rare: transient lymphadenopathy, allergic reactions (including anaphylactic reactions), neuritis, acute disseminated encephalomyelitis, Guillain-Barré syndrome*, vomiting, urticaria, pruritus, erythema, rash, angioedema, influenza-like illness, malaise
*Spontaneous reports of Guillain-Barre syndrome have been received following vaccination with Fluarix®; however, a causal association between vaccination and Guillain –Barre syndrome has not been established.

Overdose: Not applicable

Storage: 2-8C (in a refrigerator); Do not freeze.

****Full prescribing information is available upon request.**
In case of adverse events, please report to GlaxoSmithKline using the following numbers:
(02) 8129887 or 0917-8890640

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