

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Fluarix suspension for injection in a prefilled syringe
Influenza vaccine (split virion, inactivated)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Influenza virus (inactivated, split) of the following strains*:

- A/California/7/2009 (H1N1)pdm09-like strain (A/Christchurch/16/2010, NIB-74xp)
15 micrograms HA**
- A/Hong Kong/4801/2014 (H3N2) - like strain (A/Hong Kong/4801/2014, NYMC X-263B)
15 micrograms HA**
- B/Brisbane/60/2008 - like strain (B/Brisbane/60/2008, wild type)
15 micrograms HA**

per 0.5 ml dose

- * propagated in fertilized hens' eggs from healthy chicken flocks
- ** haemagglutinin

This vaccine complies with the World Health Organisation (WHO) recommendation (northern hemisphere) and EU recommendation for the **2016/2017** season.

Excipients with known effect

This product contains approximately 3.75 mg of sodium chloride and approximately 1.3 mg of disodium phosphate dodecahydrate per dose (see section 4.4).

This product contains approximately 0.2 mg of potassium dihydrogen phosphate and approximately 0.1 mg of potassium chloride per dose (see section 4.4).

Fluarix may contain traces of eggs (such as ovalbumin, chicken proteins), formaldehyde, gentamicin sulphate and sodium deoxycholate which are used during the manufacturing process (see section 4.3).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for injection in a pre-filled syringe.
The suspension is colourless to slightly opalescent.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Prophylaxis of influenza, especially those who run an increased risk of associated complications.

Fluarix is indicated in adults and children from 6 months of age.

The use of Fluarix should be based on official recommendations.

4.2 Posology and method of administration

Posology

Adults: 0.5 ml

Paediatric population

Children from 36 months onwards: 0.5 ml.

Children from 6 months to 35 months: Clinical data are limited. Dosages of 0.25 ml or 0.5 ml may be given, for detailed instructions on administering a 0.25 ml or 0.5 ml dose, see section 6.6. The dose given should be in accordance with the existing national recommendations.

For children aged < 9 years, who have not previously been vaccinated against influenza, a second dose should be given after an interval of at least 4 weeks.

Children less than 6 months: the safety and efficacy of Fluarix in children less than 6 months have not been established. No data are available.

Method of administration

Immunisation should be carried out by intramuscular or deep subcutaneous injection.

Precautions to be taken before handling or administering the medicinal product

For instructions for preparation of the medicinal product before administration, see section 6.6.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1 or to any component that may be present as traces such as eggs (ovalbumin, chicken proteins), formaldehyde, gentamicin sulphate and sodium deoxycholate.

Immunisation shall be postponed in patients with febrile illness or acute infection.

4.4 Special warnings and precautions for use

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine.

Fluarix should under no circumstances be administered intravascularly.

Antibody response in patients with endogenous or iatrogenic immunosuppression may be insufficient.

Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.

Interference with serological testing
See section 4.5.

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium-free'.

This medicine contains potassium, less than 1 mmol (39 mg) per dose, i.e. essentially ‘potassium-free’.

4.5 Interaction with other medicinal products and other forms of interaction

Fluarix 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 serology tests using the ELISA method to detect antibodies against HIV1, Hepatitis C and especially HTLV1 have been observed. The Western Blot technique disproves the false-positive ELISA test results. The transient false positive reactions could be due to the IgM response to the vaccine.

4.6 Fertility, pregnancy and lactation

Pregnancy

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.

Breastfeeding

Fluarix may be used during breastfeeding.

Fertility

No fertility data are available.

4.7 Effects on ability to drive and use machines

Fluarix has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Summary of the safety profile

The following undesirable effects have been observed during clinical trials with the following frequencies:

Very common (≥1/10)

Common (≥1/100to <1/10)

Uncommon (≥1/1,000 to <1/100)

Tabulated list of adverse reactions.

System organ class	Very common ≥1/10	Common ≥1/100 to <1/10	Uncommon ≥1/1,000 to <1/100
Nervous system disorders		Headache*	
Skin and subcutaneous tissue disorders		Sweating*	
Musculoskeletal and connective tissue disorders		Myalgia, arthralgia*	
General disorders		Fever, fatigue,	

and administration site conditions		shivering, malaise. Local reactions: pain, redness, induration, swelling, ecchymosis*	
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*These reactions usually disappear within 1-2 days without treatment.

Paediatric population

In clinical studies healthy children 6 months to 17 years of age were administered Fluarix (more than 3500 children).

In all age groups the most frequently reported local adverse reaction after vaccination was pain which occurred with a frequency of 31.9% to 52.7% of all doses.

In children up to 6 years of age the most common general adverse reaction reported is irritability in 8.1% up to 23.2% of all doses.

In age group 6 years and older, the most frequent general adverse reaction was muscle aches in 10.7% up to 24.6% of all doses.

The following adverse reactions have been reported in this age population.

System organ class	Very common ≥1/10	Common ≥1/100 to <1/10	Uncommon ≥1/1,000 to <1/100
Metabolism and nutrition disorders	Loss of appetite ²		
Psychiatric disorders	Irritability ²		
Nervous system disorders	Drowsiness ² , headache ³		
Gastrointestinal disorders		Gastrointestinal symptoms ³	
Musculoskeletal, connective tissue and bone disorders	Muscle aches ³ , joint pain ³		
General disorders and administration site conditions	Fever ² , fatigue ³ . Local reactions: pain ¹ , redness ¹ , swelling ¹	Fever ³ , shivering ³	

¹ reported in children aged from 6 months to 17 years

² reported in children aged from 6 months to <6 years

³ reported in children aged from 6 years to 17 years

Post marketing

Adverse reactions reported from post-marketing surveillance are, next to the reactions which have also been observed during the clinical trials, the following:

Blood and lymphatic system disorders:

Transient thrombocytopenia, transient lymphadenopathy

Immune system disorders:

Allergic reactions (symptoms including conjunctivitis), in rare cases leading to shock, angioedema

Nervous system disorders:

Neuralgia, paraesthesia, febrile convulsions, neurological disorders, such as encephalomyelitis, neuritis and Guillain Barré syndrome

Vascular disorders:

Vasculitis associated in very rare cases with transient renal involvement

Skin and subcutaneous tissue disorders:

Generalised skin reactions including pruritus, urticaria or non-specific rash

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie

4.9 Overdose

Overdosage is unlikely to have any untoward effect.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Influenza vaccine, ATC code: J07BB02

Seroprotection is generally obtained within 2 to 3 weeks. The duration of postvaccinal immunity to homologous strains or to strains closely related to the vaccine strains varies but is usually 6-12 months.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Non-clinical data reveal no special hazards based on conventional studies of acute toxicity, local tolerance, repeated dose toxicity, reproductive toxicity, and safety pharmacology.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride, disodium phosphate dodecahydrate, potassium dihydrogen phosphate, potassium chloride, magnesium chloride hexahydrate, α -tocopheryl hydrogen succinate, polysorbate 80, octoxinol 10 and water for injections.

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

1 year.

6.4 Special precautions for storage

Store in a refrigerator (2°C - 8°C) . Do not freeze. Keep the syringe in the outer carton in order to protect from light.

6.5 Nature and contents of container

0.5 ml suspension for injection in prefilled syringe (Type I glass) with a plunger stopper (butyl) with fixed or separate or without needles in the following pack sizes:.

- with fixed needle: pack sizes of 1, 10 or 20
- with 1 separate needle: pack sizes of 1, 10 or 20
- with 2 separate needles: pack size of 1
- without needle: pack sizes of 1, 10 or 20

Not all pack sizes maybe marketed.

6.6 Special precautions for disposal and other handling

The vaccine should be allowed to reach room temperature before use.
Shake before use. Inspect visually prior to administration.

When a dose of 0.5 ml is indicated, the entire contents of the syringe should be injected.

Instructions for administration of 0.25 ml of the vaccine for use in children from 6 months to 35 months

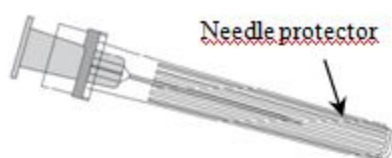
When a dose of 0.25 ml is indicated, the pre-filled syringe should be held in upright position and half of the volume should be eliminated until the stopper reaches the marking line printed on the syringe. The remaining volume of 0.25 ml should be injected.

Instructions for administration of the vaccine presented in pre-filled syringe without a fixed needle

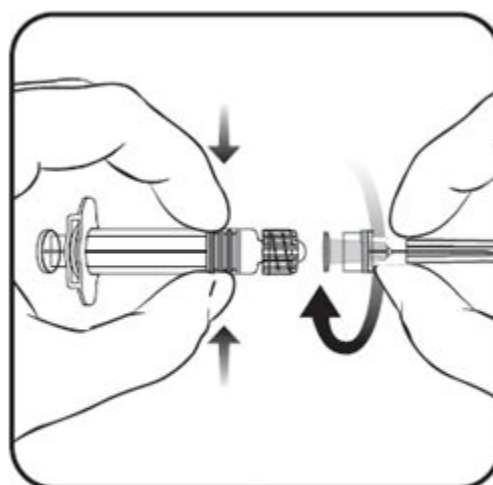
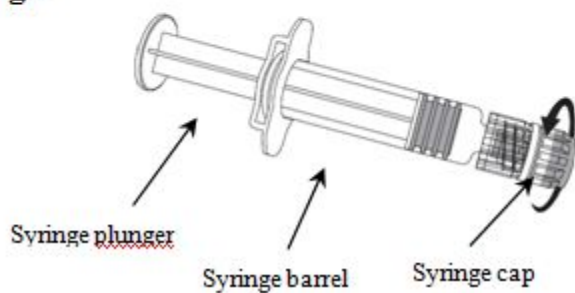
To attach the needle to the syringe, refer to picture 1.

Picture 1

Needle



Syringe



1. Holding the syringe barrel in one hand (avoid holding the syringe plunger), unscrew the syringe cap by twisting it anticlockwise.
2. To attach the needle to the syringe, twist the needle clockwise into the syringe until you feel it lock. (see picture 1)

3. Remove the needle protector, which on occasion can be a little stiff.
4. Administer the vaccine.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

GlaxoSmithKline (Ireland) Ltd
12 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1077/025/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd April 1998

Date of last renewal: 30th September 2015

10 DATE OF REVISION OF THE TEXT

April 2017