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Agency Approval Date: 16/6/2016
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Text Issue 11 Draft No.1
SPC Issue 5 Draft No.1

Package leaflet: Information for the user

Fluarix® suspension for injection in a pre-filled syringe
Influenza vaccine (split virion, inactivated)

For use during the 2016/2017 NH season

Read all of this leaflet carefully before you or your child start receiving this vaccine because it contains important formation for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This vaccine has been prescribed for you or your child only. Do not pass it on to others.
- If you or your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Fluarix is and what it used for

Fluarix is a vaccine. This vaccine helps to protect you or your child against influenza (flu), particularly in subjects who run a high risk of associated complications. The use of Fluarix should be based on official recommendations.

When a person is given the vaccine Fluarix, the immune system (the body's natural defence system) will produce its own protection (antibodies) against the disease. None of the ingredients in the vaccine can cause flu.

Flu is a disease that can spread rapidly and is caused by different types of strains that can change every year. Therefore, this is why you or your child might need to be vaccinated every year. The greatest risk of catching flu is during the cold months between October and March. If you or your child was not vaccinated in the autumn, it is still sensible to be vaccinated up until the spring since you or your child runs the risk of catching flu until then. Your doctor will be able to recommend the best time to be vaccinated.

Fluarix will protect you or your child against the three strains of virus contained in the vaccine from about 2 to 3 weeks after the injection.

The incubation period for flu is a few days, so if you or your child are exposed to flu immediately before or after your vaccination, you or your child could still develop the illness.

The vaccine will not protect you against the common cold, even though some of the symptoms are similar to flu.

2. What you need to know before you or your child receives

To make sure that Fluarix is suitable for you or your child, it is important to tell your doctor or pharmacist if any of the points below apply to you or your child. If there is anything you do not understand, ask your doctor or pharmacist to explain.

Do not use Fluarix

- if you or your child is allergic to the active substance or any of the other ingredients of this medicine (listed in section 6) or any component that may be present in very small amounts such as eggs (ovalbumin and chicken proteins), formaldehyde, gentamicin sulphate or sdoum deoxycholate:

- if you or your child has an illness with a high temperature or acute infection, the vaccination should be postponed until after you or your child has recovered.

Warnings and precautions

Talk to your doctor or pharmacist before you or your child receives Fluarix

- if you or your child has a poor immune response (immunodeficiency or taking medicines affecting the immune system).

- if, for any reason, you or your child has a blood test within a few days following a flu vaccination. This is because false positive blood test results have been observed in a few patients who had recently been vaccinated.

Fainting can occur (mostly in adolescents) following, or even before, any needle injection, therefore tell the doctor or nurse if you or your child fainted with a previous injection.

As with all vaccines, Fluarix may not fully protect all persons who are vaccinated.

Other medicines and Fluarix

Tell your doctor or pharmacist if you or your child is taking, has recently taken or might take any other medicines.

Fluarix can be given at the same time as other vaccines by using separate limbs. It should be noted that the side effects may be stronger.

The immunological response may decrease in case of immunosuppressant treatment, such as corticosteroids, cytotoxic drugs or radiotherapy.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Flu 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 flu vaccines do not indicate that the vaccine would have harmful effects on the pregnancy or the baby.

Fluarix may be used during breast-feeding.

Your doctor/pharmacist will be able to decide if you or your child should receive Fluarix. Ask your doctor or pharmacist for advice before taking any medicine.

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

Fluarix contains sodium

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

Fluarix contains potassium

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

3. How Fluarix is given

Dosage

Adults receive one 0.5 ml dose.

Use in children:
Children from 36 months and older receive one 0.5 ml dose.
Children from 6 months to 35 months may receive either one 0.25 ml dose or one 0.5 ml dose in accordance with existing national recommendations**.**
If your child is younger than 9 years of age and has not been previously vaccinated against flu, a second dose should be given after at least 4 weeks.

Method and/or route of administration

Your doctor will administer the recommended dose of the vaccine as an injection into the muscle or deep under the skin.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this vaccine can cause side effects, although not everybody gets them.

During clinical trials, the following side effects have been observed. Their frequencies have been estimated as common (affects 1 to 10 users in 100):

- headache
- sweating
- muscular pain (myalgia), joint pain (arthralgia)
- fever, generally feeling unwell (malaise), shivering, fatigue
- local reactions: redness, swelling, pain, bruising (ecchymosis), hardness (induration) around the area where the vaccine is injected.

These reactions usually disappear within 1-2 days without treatment.

The following side effects have been reported during clinical trials in children and adolescents from 6 months to 17 years of age:

Very common (these may occur with more than 1 in 10 doses of the vaccine):

- irritability[2]
- loss of appetite[2]
- drowsiness[2]
- headache[3]
- joint pain[3]
- muscle aches[3]
- fever[2]
- fatigue[3]
- local reactions: redness[1], swelling[1], pain[1]

Common (these may occur with up to 1 in 10 doses of the vaccine):

- gastrointestinal symptoms[3]
- shivering[3]
- fever[3]

[1] reported in children 6 months to 17 years of age
[2] reported in children 6 months to <6 years of age
[3]reported in children 6 years to 17 years of age

Next to the above common side effects, the following side effects occurred after the vaccine came on the market:

- allergic reactions:
  - discharge with itching of the eyes and crusty eyelids (conjunctivitis)
  - leading to medical emergency with a failure of the circulatory system to maintain adequate blood flow to the different organs (shock) in rare cases,
  - swelling most apparent in the head and neck, including the face, lips, tongue, throat or any other part of the body (angioedema) in very rare cases.
- skin reactions that may spread throughout the body including itchiness of the skin (pruritus, urticaria), rash
- blood vessel inflammation which may result in skin rashes (vasculitis) and in very rare cases in temporary kidney problems.
- pain situated on the nerve route (neuralgia), anomalies in the perception of touch, pain, heat and cold (paraesthesia), fits (convulsions) associated with fever, neurological disorders that may result in stiff neck, confusion, numbness, pain and weakness of the limbs, loss of balance, loss of reflexes, paralysis of part or all the body (encephalomyelitis, neuritis, Guillain-Barré syndrome)
- temporary reduction in the number of certain types of particles in the blood called platelets; a low number of these can result in excessive bruising or bleeding (transient thrombocytopenia); temporary swelling of the glands in the neck, armpit or groin (transient lymphadenopathy)

Reporting of side effects
If you or your child get any side effects, talk to your doctor or pharmacist This includes any possible side effects not listed in this leaflet. You can also report side effects directly via
Ireland
HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Fax: +353 1 6762517. Website: www.hpra.ie; email: medsafety@hpra.ie
United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fluarix

Keep this vaccine out of the sight and reach of children.

Do not use this vaccine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C - 8°C).

Do not freeze.

Store in the original package in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Fluarix contains

- The active substance is: 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 fertilised hens' eggs from healthy chicken flocks
** haemagglutinin

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

- The other ingredients are: 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.

What Fluarix looks like and contents of the pack

Fluarix is a suspension for injection presented in a pre-filled syringe 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 may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
In the UK: SmithKline Beecham Ltd, Stockley Park West, Uxbridge, Middlesex UB11 1BT
In Ireland: GlaxoSmithKline (Ireland) Ltd., 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland

Manufacturer:
GlaxoSmithKline Biologics, Branch of SmithKline Beecham Pharma GmbH & Co. KG, Zirkusstrasse 40, D-01069, Dresden, Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

Member State	**Name**
Austria, Bulgaria, Cyprus, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Malta, The Netherlands, Norway, Poland, Portugal, Romania, Slovenia, Slovakia, Spain, Sweden, UK	Fluarix
Belgium, Luxemburg	α-RIX
Germany	Influsplit SSW

Other formats:
To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only)
Please be ready to give the following information:
Product name **Fluarix**
Reference number 10592/0118
This is a service provided by the Royal National Institute of Blind People.

This leaflet was last updated in May 2016

The following information is intended for healthcare professionals only.

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.

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

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Fluarix should under no circumstances be administered intravascularly.

Fluarix may be given at the same time as other vaccines. Immunisation should be carried out on separate limbs.

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.

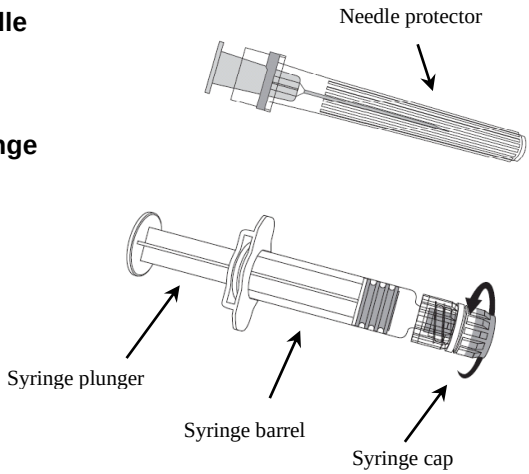
Instructions for administration of 0.25 ml of the vaccine for use in children from 6 months to 35 months
When a dose of 0.25 ml is indicated, the pre-filled syringe should be held in upright position and half of the volume should be eliminated until the stopper reaches the marking line printed on the 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

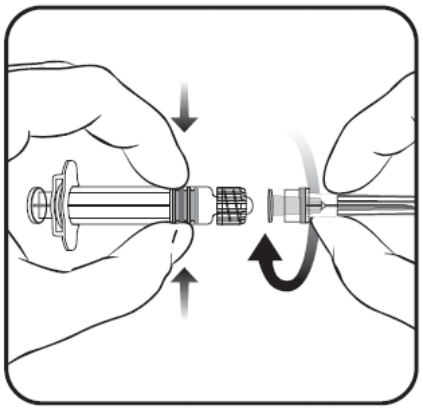
To attach the needle to the syringe, refer to picture 1.

Needle

Syringe



Picture 1



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)
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.

This leaflet was last updated in May 2016
Fluarix is a registered trade mark of the GSK group of companies