

PACKAGE LEAFLET: INFORMATION FOR THE USER

enzira[®] Suspension for injection, pre-filled syringe
Influenza vaccine (split virion, inactivated)

Read all of this leaflet carefully before you or your child are vaccinated because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This vaccine has been prescribed for you or your child only. Do not pass it on to others.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What ENZIRA is and what it is used for
2. What you need to know before you or your child use ENZIRA
3. How to use ENZIRA
4. Possible side effects
5. How to store ENZIRA
6. Contents of the pack and other information

1. What ENZIRA is and what it is used for

ENZIRA is a vaccine. This vaccine helps to protect you or your child against influenza (flu), particularly in people who run a high 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.

When a person is given the vaccine ENZIRA, 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 were not vaccinated in the autumn, it is still sensible to be vaccinated up until the spring since you or your child run the risk of catching flu until then. Your doctor will be able to recommend the best time to be vaccinated.

ENZIRA will help protect you or your child against the three strains of virus contained in the vaccine from about 2-3 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 or your child 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 use ENZIRA

To make sure that ENZIRA 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 ENZIRA

- If you or your child are allergic to:
 - the active substances, or
 - any of the other ingredients of this vaccine (listed in section 6), or
 - any component that may be present in small amounts, such as eggs (ovalbumin or chicken proteins) or the antibiotics neomycin or polymyxin.
- If you or your child have an illness with a high temperature or acute infection, the vaccination shall be postponed until after you or your child have recovered.

Warnings and precautions

ENZIRA is not indicated for children less than 5 years of age.

Talk to your doctor before using ENZIRA if you or your child have a poor immune response (immunodeficiency or taking medicines affecting the immune system).

Your doctor will decide if you or your child should receive the vaccine.

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

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

Other medicines and ENZIRA

- Tell your doctor or pharmacist if you or your child are taking, have recently taken or might take any other vaccines or any other medicines.
- ENZIRA 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, breast-feeding and fertility

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before receiving the vaccine. Your doctor or pharmacist will be able to decide if you should receive ENZIRA.

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.

ENZIRA may be used during breast-feeding.

Driving and using machines

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

ENZIRA contains ovalbumin, potassium and sodium.

ENZIRA does not contain more than 1 µg ovalbumin per dose (0.5 ml).
This vaccine contains less than 1 mmol potassium (39 mg) per dose, i.e. essentially “potassium free”.
This vaccine contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially “sodium free”.

3. How to use ENZIRA

Dosage

Adults receive one 0.5 ml dose.

Use in children

Children from 5 years and older receive one 0.5 ml dose.

If your child is younger than 9 years of age and has not previously been vaccinated against flu, a second dose should be given after at least 4 weeks.

Method and/or route(s) 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 product, ask your doctor or pharmacist.

4. Possible side effects

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

During clinical trials, the following side effects were reported with the use of ENZIRA.

Adults and elderly

Very common (may affect more than 1 in 10 people)

- headache
- muscular pain (myalgia)
- fever, generally feeling unwell (malaise)
- local reactions: redness, swelling, pain, tenderness, hardness (induration) around the injection site

Common (may affect up to 1 in 10 people)

- nausea/vomiting
- chills/shivering
- bruising (ecchymosis) at the injection site
- joint pain

Children and adolescents from 5 to less than 18 years

Very common (may affect more than 1 in 10 people)

- headache
- muscular pain (myalgia)
- fever, generally feeling unwell (malaise)
- local reactions: pain, redness, swelling, hardness (induration) around the injection site
- irritability

Common (may affect up to 1 in 10 people)

- nausea/vomiting
- diarrhoea, loss of appetite
- cold/flu like symptoms, cough, runny/blocked nose, sneezing, sore throat
- itching around the injection site
- stomach pain

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

- allergic reactions (which may occur immediately):
 - leading to medical emergency with a failure of the circulatory system to maintain adequate blood flow to the different organs (shock) in rare cases,
 - may include symptoms of swelling of the face, lips, tongue or throat.
- 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 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 (thrombocytopenia); temporary swelling of the glands in the neck, armpit or groin (transient lymphadenopathy)
- large injection site swelling (sometimes reported as cellulitis)
- influenza-like illness

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this vaccine.

Ireland

HPRA Pharmacovigilance
 Earlsfort Terrace
 IRL - Dublin 2
 Tel: +353 1 6764971
 Fax: +353 1 6762517
 Website: www.hpra.ie
 e-mail: medsafety@hpra.ie

United Kingdom

Yellow Card Scheme
 Tel: Freephone 0800 100 3352
 Website: www.mhra.gov.uk/yellowcard

5. How to store ENZIRA

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

Do not use ENZIRA 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 to 8°C). Do not freeze.

Keep the syringe in the outer carton in order to protect from light.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What ENZIRA contains:

The active substance is influenza virus* (inactivated with β -Propiolactone, split) of the following strains:

A/Michigan/45/2015 (H1N1)pdm09 – like strain (A/Singapore/GP1908/2015, IVR-180A)	15 micrograms HA**
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A/Singapore/INFIMH-16-0019/2016 (H3N2) – like strain (A/Singapore/INFIMH-16-0019/2016, IVR-186)	15 micrograms HA**
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B/Colorado/06/2017 – like strain (B/Maryland/15/2016, wild type)	15 micrograms HA**
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per 0.5 ml dose.

* propagated in fertilised hens' eggs from healthy chicken flocks

** haemagglutinin

This vaccine complies with the WHO (World Health Organization) recommendations (Northern Hemisphere) and EU decision for the 2018/2019 season.

The other ingredients are:

Sodium chloride, anhydrous disodium phosphate, sodium dihydrogen phosphate dihydrate, potassium chloride, potassium dihydrogen phosphate, calcium chloride and water for injections.

What ENZIRA looks like and contents of the pack

ENZIRA is a 0.5 ml suspension for injection presented in a pre-filled syringe with plunger stopper (chlorobutyl rubber) with or without attached needle in pack sizes of 1 or 10. The syringe with attached needle may be supplied with or without needle-trap.

The suspension is a clear to slightly opaque liquid with some sediment that resuspends upon shaking.

Marketing Authorisation Holder and Manufacturer

Seqirus GmbH, Emil-von-Behring-Strasse 76, 35041 Marburg, Germany

Distributor:

Pfizer Limited, Sandwich, Kent CT13 9NJ, UK

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

AFLURIA®

Belgium, Czech Republic, Denmark, Finland, Germany, Greece, Italy, Luxembourg, Norway, Portugal, Romania, Spain, Sweden, The Netherlands

ENZIRA®

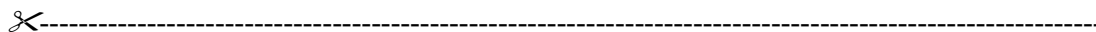
Ireland, United Kingdom

Influenza Vaccine (split virion, inactivated) Ph Eur

United Kingdom

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This leaflet was last revised in June 2018



The following information is intended for medical or healthcare professionals only

Precaution:

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 $\geq 1/1000$ to $< 1/100$)*.

An increased number of reports of fever was also reported in the age group 5 to less than 9 years. Therefore in this age group a decision to vaccinate with ENZIRA should be based on careful consideration of potential benefits and risks in the individual.

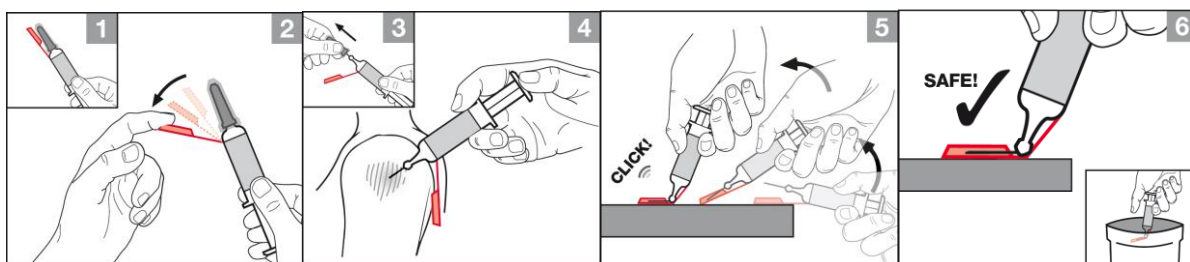
On the basis of the increased risk of febrile convulsions in children less than 5 years of age, the vaccine indication has been restricted to use in adults and children from 5 years of age only.

(*estimated from epidemiological investigations)

Instructions for use and handling

- As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following administration of the vaccine.
- The vaccine should be allowed to reach room temperature before use. Shake before use. The vaccine should appear as a homogenous clear to slightly opaque liquid suspension with some sediment that resuspends upon shaking. The vaccine must be inspected visually prior to administration and should not be used if there is any variation of physical appearance.
- ENZIRA is presented as a single use syringe and any unused product or waste material should be disposed of in accordance with local requirements.
- This vaccine is not to be injected directly into any blood vessel.

For administration using the syringe with attached needle and needle-trap, refer to the diagrams below.



1-2: Bend the orange plastic needle-trap toward the side.

3-4: Remove the translucent plastic needle-shield cover and grey needle-shield and perform the injection. Intramuscular administration of influenza vaccine should be undertaken by injection into the deltoid muscle of the upper arm.

5: Place the orange needle-trap against a stable, hard surface and then press down the trap by bending the syringe. Continue the motion until the needle is bent by approximately 90 degrees and the needle audibly clicks into the trap.

6: The needle is now secured for safe disposal in accordance with local requirements.

(See also section 3. How to use ENZIRA)