Patient Information Leaflet: Information for the user

3Fluart suspension for injection
for the 2018/2019 season
Influenza vaccine (whole virus, inactivated, adjuvanted)

- **Read all of this leaflet carefully before getting 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 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 3Fluart is and what it is used for

This vaccine helps to protect you or your child against influenza, particularly in subjects who run a high risk of associated complications.

The vaccine provides protection against diseases caused by influenza strains whose antigen structure is similar to or identical with the prototype strains of the vaccine. The vaccine does not provide protection against influenza-like diseases caused by other pathogens.

The use of 3Fluart should be based on official recommendations.

2. What you need to know before you use 3Fluart

Do not use 3Fluart

- if you are allergic to the active substances or any of the other ingredients of 3Fluart (listed in section 6), such as thiomersal, traces of ovalbumin residue, formaldehyde, gentamicin, neomycin, vancomycin or ciprofloxacin.
- if you have serious complications with regard to previous vaccination in your medical history: encephalitis, encephalopathy, non-febrile seizures, Guillain-Barré syndrome, vasculitis, neuritis, facial paresis.
- if you have acute infection or febrile illnes. In such cases the vaccine can be administered only 2-3 days after the symptoms disappear.
- for children under 3 years of age.

Warnings and precautions
Please consult your doctor, pharmacist or healthcare professional before using 3Fluart if you or your child have experienced allergic reactions, hypersensitivity, or other serious complications with regard to previous vaccination or in case you receive immunosuppressant treatment.

Extra precaution should be taken in patients with known increased susceptibility to febrile seizure, since febrile conditions may appear as an undesirable effect of vaccination. In such cases increased monitoring of the patients after vaccination and prevention of fever is recommended.

The 3Fluart suspension for injection should under no circumstances be administered intravascularly.

Children
Do not give 3Fluart to children under 3 years of age.

Other medicines and 3Fluart
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In certain cases, for example immunosuppressant treatment, the expected immunological response after vaccination may be decreased. Please tell your doctor if you are receiving immunomodulant treatment (medicines modifying the immune response).

Based on the results of clinical trials on adults (over 18 years of age) seasonal and pandemic vaccine of the manufacturer can be given at the same time on separate limbs.

Pregnancy, breast-feeding and fertility
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 using 3Fluart.

Vaccination of pregnant women is recommended only after careful evaluation of the influenza and its associated complications and the undesirable effects of the vaccination.
The 3Fluart suspension for injection can be used during breast-feeding.

Driving and using machines
3Fluart suspension for injection has no or negligible influence on the ability to drive and use machines.

3Fluart contains thiomersal
The vaccine contains thiomersal (organomercuric compound) as a preservative; and therefore you or your child may experience allergic reactions. Please tell your doctor, if you or your child are allergic to mercury or its compounds.

3. How to use 3Fluart

Posology:
Adults and elderly people: 1x0.5 ml

Use in children and adolescents
Adolescents above 12 years of age: 1x0.5 ml
Children between 3-11 years of age: 1x0.25 ml

Route and/or method of administration

Your doctor will administer the recommended dose of the vaccine as an injection into the muscle (intramuscularly).
The 3Fluart suspension for injection should under no circumstances be administered intravascularly.

Immunization should be carried out by a single injection.

The immune response develops in approximately 2-3 weeks and lasts for several months. Therefore, vaccination is best administered before the epidemic period.

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

4. Possible side effects

Like all medicines, 3Fluart can cause side effects, although not everybody gets them.

As the vaccine contains inactivated virion, influenza infection cannot be caused by vaccination.
Any respiratory disease after vaccination is only a coincidence and is caused by another respiratory pathogen.
The most common adverse reaction following injection is erythema (redness of the skin) or vaccination site pain which usually disappears within 48 hours.

Side effects observed in clinical trials

Adults:

Very common (may affect more than 1 in 10 people): pain around the area of the vaccination.

Common (may affect up to 1-10 in 100 people): injection site redness around the area of the vaccination, swelling, hardness (induration) stupor, headache, fever, malaise, muscle pain.

Uncommon (may affect up to 1-10 in 1,000 people): haematoma around the area of the vaccination, shivering, fatigue, arthralgia, pain in extremity

Rare (may affect up to 1-10 in 10,000 people): nausea, numbness (numbness in arm, vaccination site), sweating, dizziness, hives/urticaria.

Not known (frequency cannot be estimated from the available data): pallor, erythema (redness of former vaccination sites, redness of existing papilla), dysphonia.

Additional side effects in children

Frequency of adverse effects reported in clinical trials in children and adolescents above 3 years is the same than in adults.

Adverse reactions reported from post-marketing surveillance**

Not known (frequency cannot be estimated from the available data): weakness, vaccination site warmth, burning sensation on skin, rash, itching, allergic reactions.

In unique cases Parsonage-Turner syndrome*, paresis*, or paralysis of the nervus trochlearis (nerve of the eye movement muscle)* and reduction in platelet count (in case of patients with idiopathic thrombocytopenic purpura) were reported. Their relation to the vaccination has not been verified, but cannot be excluded.

* the above adverse events occurred upon co-administration with pandemic monovalent influenza vaccine.
** side effects observed after vaccination with the seasonal influenza vaccine containing higher dose of virus strains than the 3Fluart.

Other possible complications according to literature include neuritis, encephalopathy, Guillain-Barré syndrome, Gianotti-Crosti syndrome (with mild general symptoms such as fever, swelling of the lymphatic gland, liver and spleen enlargement furthermore with skin symptoms, such as purulent, non-itching, pale or dark red rashes on the face and the limbs).

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 via the national reporting system listed in Appendix V.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store 3Fluart

Store 3Fluart in a refrigerator at (2°C - 8°C).
Do not freeze.
Store in the original package in order to protect from light.

Do not use this medicine after the expiry date (EXP.:) which is stated on the label.

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

Use the vaccine immediately after opening.

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 3Fluart contains

- Composition of 1 dose (0.5 ml) vaccine for the 2018/2019 season:

The vaccine contains formaldehyde-inactivated whole virion* with the following antigen composition:

A/Michigan/45/2015 (H1N1)pdm09-like strain (A/Michigan/45/2015, NYMC X-275)	6 µg HA**
A/Singapore/INFIMH-16-0019/2016 (H3N2)-like strain (A/Singapore/INFIMH-16-0019/ 2016, IVR-186)	6 µg HA**
B/Colorado/06/2017-like strain (B/Maryland/15/2016, NYMC BX-69A)	6 µg HA**

* propagated in embryonated hens' eggs
** haemagglutinin

This vaccine complies with the World Health Organisation (WHO) recommendation (northern hemisphere) and EU recommendation for the 2018/2019 season.

- Excipients: aluminum chloride hexahydrate, trisodium phosphate dodecahydrate, potassium chloride, thiomersal, disodium hydrogen phosphate dihydrate, potassium dihydrogen phosphate, sodium chloride, water for injection.

Adjuvant: aluminum-phosphate gel (max. 0.625 milligram Al^{3+})
Aluminum content: max. 0.625 milligram Al^{3+}/0.5ml
Thiomersal content: max. 53 microgram/0.5ml

A single dose contains a maximum of 1 μg of ovalbumin, 0.5 μg of gentamicin, neomycin, vancomycin and ciprofloxacin.

What 3Fluart looks like and contents of the pack
Off-white, slightly opalescent suspension that becomes homogenous after shaking.

0.5 ml suspension filled in an ampoule (Type I glass) with a breaking point.
Pack size of 1: One ampoule, one sterile safety syringe with retractable needle in a box.

Pack size of 20: One box contains 20 ampoules.

Marketing Authorization Holder and Manufacturer
Fluart Innovative Vaccines Ltd.
H-2097 Pilisborosjenő
Fő u.7.

OGYI-T-8998/03	1×0.5 ml	in glass ampoule
OGYI-T-8998/04	20×0.5 ml	in glass ampoule

This leaflet was last revised in September 2018

The following information is intended for healthcare professionals only:

The vaccine should be allowed to reach room temperature before use.
Shake well before opening. Check the homogeneity of the suspension after shaking. Inhomogeneous vaccines should not be used!

The vaccine should be administered intramuscularly, in the deltoid muscle of the upper arm, by means of the supplied sterile safety syringe and needle after careful disinfection of the injection site.

For children aged 3-11 years: the total volume of the homogenized vaccine should be drawn up into the supplied sterile safety syringe and needle, then by holding the syringe upright, a portion of the vaccine should be expelled out of the syringe so that exactly 0.25 ml of the vaccine remains in the syringe. Inject the remaining 0.25 ml content of the syringe intramuscularly after skin disinfection, into the deltoid muscle of the upper arm.

The 3Fluart suspension for injection should under no circumstances be administered intravascularly.

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

THE USAGE OF THE SAFETY SYRINGE:

- Withdrawing the plunger of the safety syringe to the end position retracts the needle, and makes further use impossible.
- Open the syringe as indicated on the package and ensure that the plunger is not fully depressed beyond the first graduation mark of the safety syringe scale.
- Inject the vaccine by fully depressing plunger, then withdraw the plunger to retract the needle safely back to the barrel of the syringe.