PACKAGE LEAFLET

Package leaflet: Information for the user

Adjuvanted Trivalent Influenza Vaccine (Surface Antigen, Inactivated) Suspension for Injection in Pre-filled Syringe 2020/2021

Influenza Vaccine, Adjuvanted with MF59C.1

Read all of this leaflet carefully before you receive this vaccine 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 or pharmacist.
- This vaccine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get 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 Adjuvanted Trivalent Influenza Vaccine (Surface Antigen, Inactivated) is and what it is used for

Adjuvanted Trivalent Influenza Vaccine (Surface Antigen, Inactivated) is a vaccine. This vaccine helps to protect you against influenza (flu). It is used as active immunisation in the elderly (of 65 years of age and over), particularly in people with an increased risk of associated complications. Adjuvanted Trivalent Influenza Vaccine (Surface Antigen, Inactivated) should be used in accordance with the official recommendations.

Through vaccination with Adjuvanted Trivalent Influenza Vaccine (Surface Antigen, Inactivated), the immune system (the body's natural defence system) is stimulated to produce its own protection (antibodies) against the illness. None of the ingredients of this vaccine can by itself 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 might need to be vaccinated every year. The greatest risk of catching flu is during the cold months between October and March. If you were not vaccinated in the autumn, it is still sensible to be vaccinated up until the spring since you run the risk of catching flu until then. Your doctor will be able to recommend the best time to be vaccinated.

Adjuvanted Trivalent Influenza Vaccine (Surface Antigen, Inactivated) will protect you against the three strains of virus contained in the vaccine from about 2 to 3 weeks after the injection.

As the incubation period (the time between being infected with a disease pathogen and the occurrence of the first symptoms) for flu is several days, you could still develop the illness if you are exposed to flu immediately before or after your vaccination.

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 use Adjuvanted Trivalent Influenza Vaccine (Surface Antigen, Inactivated)

To make sure that Adjuvanted Trivalent Influenza Vaccine (Surface Antigen, Inactivated) is suitable for you, it is important to tell your doctor or pharmacist if any of the points below apply to you. If there is anything you do not understand, ask your doctor or pharmacist to explain.

Do not use Adjuvanted Trivalent Influenza Vaccine (Surface Antigen, Inactivated)
- if you are allergic (hypersensitive) to the active substances, to any of the ingredients of Adjuvanted Trivalent Influenza Vaccine (Surface Antigen, Inactivated), to eggs, to chicken proteins, such as ovalbumin, to kanamycin and neomycin sulphate, to formaldehyde, cetyltrimethyl ammonium bromide (CTAB) and to hydrocortisone
  (For information about the other ingredients of Adjuvanted Trivalent Influenza Vaccine (Surface Antigen, Inactivated) see section 6 "**Contents of the pack and other information**") or
- if you have had an anaphylactoid reaction to previous influenza vaccination.
- if you have an illness with a high temperature or acute infection, the vaccination shall be postponed until after you have recovered.

Warnings and precautions
You should tell your doctor before vaccination if you have a poor immune response (immunodeficiency or taking medicines affecting the immune system).

Fainting, feeling faint or other stress-related reactions can occur as a response to any needle injection. Tell your doctor or nurse if you have experienced this kind of reaction previously.

Your doctor will decide if you should receive the vaccine.

If, for any reason, you 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, Adjuvanted Trivalent Influenza Vaccine (Surface Antigen, Inactivated) may not fully protect all persons who are vaccinated.

It is possible that a protective immune response will not be triggered in all vaccinated persons.

Latex-sensitive individuals:
Although no natural rubber latex is detected in the syringe tip cap, the safe use of Adjuvanted Trivalent Influenza Vaccine (Surface Antigen, Inactivated) in latex-sensitive individuals has not been established.

Other medicines and Adjuvanted Trivalent Influenza Vaccine (Surface Antigen, Inactivated)
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If Adjuvanted Trivalent Influenza Vaccine (Surface Antigen, Inactivated) needs to be used at the same time as other vaccines, immunization should be carried out by injecting into separate limbs. It should be noted that the side effects may be more intense if given at the same time as other vaccines.

A higher frequency of some solicited systemic reactions has been reported in subjects vaccinated with trivalent inactivated influenza vaccine and pneumococcal vaccine compared with trivalent inactivated influenza vaccine alone.

The immunological response may decrease in patients also receiving immunosuppressant treatment, such as corticosteroids, cytotoxic drugs or radiotherapy.
Pregnancy and breast-feeding

Not applicable.

Driving and using machines
Adjuvanted Trivalent Influenza Vaccine (Surface Antigen, Inactivated) has no or negligible influence on the ability to drive and use machines.

Important information about some of the ingredients of Adjuvanted Trivalent Influenza Vaccine (Surface Antigen, Inactivated)
One dose of Adjuvanted Trivalent Influenza Vaccine (Surface Antigen, Inactivated) (0.5 ml) contains less than 1 mmol (39 mg) potassium and less than 1 mmol (23 mg) sodium. This means that Adjuvanted Trivalent Influenza Vaccine (Surface Antigen, Inactivated) is essentially free from potassium and sodium.

Adjuvanted Trivalent Influenza Vaccine (Surface Antigen, Inactivated) does not contain more than 0.2 micrograms of ovalbumin per 0.5 ml dose.

3. How to use Adjuvanted Trivalent Influenza Vaccine (Surface Antigen, Inactivated)

Dose
One 0.5 ml dose.

Route(s) and/or method of administration
Your doctor will administer the recommended dose of the vaccine as an injection in the upper arm muscle (deltoid muscle).

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

4. Possible side effects

Like all medicines, Adjuvanted Trivalent Influenza Vaccine (Surface Antigen, Inactivated) can cause side effects, although not everybody gets them.

More mild post-immunisation reactions were reported with Adjuvanted Trivalent Influenza Vaccine (Surface Antigen, Inactivated) compared to non-adjuvanted influenza vaccines.
During clinical trials, the following side effects have been observed:

Frequencies estimated as very common (affects 1 or more users in 10):
- headache
- muscular pain (myalgia)
- tenderness, pain at injection site, fatigue

Frequencies estimated as common (affects 1 to 10 users in 100):
- nausea, diarrhoea, vomiting
- sweating
- joint pain (arthralgia)
- fever, generally feeling unwell (malaise), shivering
- local reactions: redness, swelling, bruising (ecchymosis), hardness (induration) around the area where the vaccine is injected

Frequency estimated as uncommon (affects 1 to 100 users in 1000):
- rash

Most reactions are mild or moderate and resolve spontaneously within 1 to 2 days.

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

- 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); swelling of the glands in the neck, armpit or groin (lymphadenopathy)
- asthenia, Influenza-like Illness (ILI)
- swelling, pain and redness at the injection site extending to more than 10 cm and lasting more than one week (Injection site cellulitis-like reaction)
- extensive swelling of injected limb lasting more than one week
- allergic reactions:
    - sudden fall in blood pressure (anaphylaxis) that in rare cases can lead to failure of the circulatory system to maintain adequate blood flow to the different organs (shock)
    - swelling most apparent in the head and neck, including the face, lips, tongue, throat or any other part of the body (angioedema)
- pain in the extremity, muscular weakness
- pain situated on the nerve route (neuralgia), anomalies in the perception of touch, pain, heat and cold (paraesthesia), fits (convulsions), fainting, feeling faint (syncope, presyncope), 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)
- skin reactions that may spread throughout the body including itchiness of the skin (pruritus, urticaria), rash
- severe skin rash (erythema multiforme)
- blood vessel inflammation which may result in skin rashes (vasculitis) and in very rare cases in temporary kidney problems

Reporting of side effects
If you 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 the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Adjuvanted Trivalent Influenza Vaccine (Surface Antigen, Inactivated)

Keep out of the sight and reach of children.

Do not use Adjuvanted Trivalent Influenza Vaccine (Surface Antigen, Inactivated) 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 refrigerator (2°C – 8°C). Do not freeze. Keep the syringe in the outer carton 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 to protect the environment.

6. Contents of the pack and other information

What Adjuvanted Trivalent Influenza Vaccine (Surface Antigen, Inactivated) contains

- The active substances are: influenza virus surface antigens (haemagglutinin and neuraminidase), of the following strains*:

A/Guandong-Maonan/SWL1536/2019 (H1N1)pdm09-like strain (A/Victoria/2454/2019 IVR-207)
15 micrograms HA**

A/Hong Kong/2671/2019 (H3N2)-like strain (A/Hong Kong/2671/2019 IVR-208)
15 micrograms HA**

B/Washington/02/2019-like strain (B/Victoria/705/2018 BVR-11)
15 micrograms HA**

per 0.5 ml dose

* propagated in fertilized hens' eggs from healthy chicken flocks and adjuvanted with MF59C.1
** haemagglutinin

This vaccine complies with the World Health Organisation (WHO) recommendation (northern hemisphere) and EU recommendation for the 2020/2021 season.

- The adjuvant is: MF59C.1: 9.75 mg squalene; 1.175 mg polysorbate 80; 1.175 mg sorbitan trioleate; 0.66 mg sodium citrate; 0.04 mg citric acid and water for injections.

- The other ingredients are: sodium chloride, potassium chloride, potassium dihydrogen phosphate, disodium phosphate dihydrate, magnesium chloride hexahydrate, calcium chloride dihydrate and water for injections.

What Adjuvanted Trivalent Influenza Vaccine (Surface Antigen, Inactivated) looks like and contents of the pack

The vaccine is a suspension for injection in a pre-filled syringe of 0.5 ml in box of 1 or 10, with or without needle.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Seqirus UK Limited
Level 3, 29 Market Street, Maidenhead SL6 8AA, United Kingdom.

Manufacturer

Seqirus Vaccines Ltd.
Gaskill Road, Speke Liverpool L24 9GR, United Kingdom

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

United Kingdom: Fluad

This leaflet was last revised in 29/06/2020.

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.

The vaccine should be allowed to reach room temperature before use.
Gently shake before use.
Do not use if the vaccine has been frozen.
After shaking, the normal appearance of Adjuvanted Trivalent Influenza Vaccine (Surface Antigen, Inactivated) is a milky-white suspension. Visually inspect the contents of each Adjuvanted Trivalent Influenza Vaccine (Surface Antigen, Inactivated) pre-filled syringe for particulate matter or discoloration prior to administration. If either condition is observed, do not use the contents.
When using a pre-filled syringe supplied without a needle, remove the tip cap from the syringe and then attach a suitable needle for administration. For Luer Lock syringes, remove the tip cap by unscrewing it in a counter-clockwise direction. Once the tip cap is removed, attach a needle to the syringe by screwing it on in a clockwise direction until it locks. Once the needle is locked in place, remove the needle protector and administer the vaccine.
It must not be mixed with other medicinal products.
The vaccine should under no circumstances be administered intravascularly or subcutaneously.
The vaccine is administered by intramuscular injection into the deltoid muscle. Due to the presence of the adjuvant, the injection should be carried out by using a 25 mm needle.