Package leaflet: Information for the user

Adjuvanted Trivalent Influenza Vaccine (Surface Antigen, Inactivated) Seqirus suspension for injection in pre-filled syringe
Influenza vaccine, Adjuvanted with MF59C.1

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you receive this medicine 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.
- 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 Adjuvanted Trivalent Influenza Vaccine Seqirus** is and what it is used for

Adjuvanted Trivalent Influenza Vaccine Seqirus is a vaccine against flu (influenza).
When a person is given the vaccine, the immune system (the body's natural defence system) will produce its own protection against the influenza virus. None of the ingredients in the vaccine can cause flu.

This vaccine is used to prevent flu in adults of 50 years of age and older.

This vaccine targets three strains of influenza virus following the recommendations by the World Health Organisation for the 2025/2026 season.

2. What you need to know before you receive Adjuvanted Trivalent Influenza Vaccine Seqirus

You should not receive Adjuvanted Trivalent Influenza Vaccine Seqirus

- If you are allergic to
  - the active ingredients or any of the other ingredients of this medicine (listed in section 6)
  - egg or chicken proteins (such as ovalbumin), kanamycin and neomycin sulphate, formaldehyde, cetyltrimethylammonium bromide (CTAB) and hydrocortisone, which are trace residues from the manufacturing process.
- If you have had a severe allergic reaction (e.g. anaphylaxis) to previous influenza vaccination.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before receiving Adjuvanted Trivalent Influenza Vaccine Seqirus.

BEFORE receiving the vaccine
- Your doctor or nurse will make sure that appropriate medical treatment and supervision is readily available in case of a rare anaphylactic reaction (a very severe allergic reaction with symptoms such as difficulty in breathing, dizziness, a weak and rapid pulse and skin rash) following the administration. This reaction may occur with Adjuvanted Trivalent Influenza Vaccine Seqirus as with all vaccines that are injected.
- You should tell your doctor if you have an illness associated with fever. Your doctor may decide to delay your vaccination until your fever is gone.
- You should tell your doctor if your immune system is impaired, or if you are undergoing treatment which affects the immune system, e.g. with medicine against cancer (chemotherapy) or corticosteroid medicines (see Section "Other medicines and Adjuvanted Trivalent Influenza Vaccine Seqirus").
- You should tell your doctor if you have a bleeding problem or bruise easily.
- Fainting can occur following, or even before, any needle injection, therefore tell the doctor or nurse if you fainted with a previous injection.

As with all vaccines, Adjuvanted Trivalent Influenza Vaccine Seqirus may not fully protect all persons who are vaccinated.

Children
Adjuvanted Trivalent Influenza Vaccine Seqirus is not recommended for use in children.

Other medicines and Adjuvanted Trivalent Influenza Vaccine Seqirus
Tell your doctor or nurse if you are using, have recently used or might use any other medicines, including medicines obtained without a prescription or if you have recently received any other vaccine.

Pregnancy and breast-feeding
This vaccine is for use in adults 50 years and older. It is not to be used in women who are, or may be, pregnant or breast-feeding.

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

Adjuvanted Trivalent Influenza Vaccine Seqirus contains potassium and sodium
This vaccine contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium free'.
This vaccine contains potassium, less than 1 mmol (39 mg) per dose, i.e. essentially 'potassium free'.

3. How Adjuvanted Trivalent Influenza Vaccine Seqirus is given

Adjuvanted Trivalent Influenza Vaccine Seqirus is given by your doctor or nurse as an injection into the muscle at the top of the upper arm (deltoid muscle).

Adults of 50 years of age and older:

One dose of 0.5 ml

4. Possible side effects

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you experience the following serious side effect – you may need urgent medical attention or hospitalisation:

- Difficulty in breathing, dizziness, a weak and rapid pulse and skin rash which are symptoms of an anaphylactic reaction (a very severe allergic reaction)

The following side effects have been reported during clinical trials in adults 50 years of age and older.

Very common (may affect more than 1 in 10 people):
- Pain at injection site
- Fatigue
- Headache
- Joint pain (arthralgia)
- Muscular pain (myalgia)

Common (may affect up to 1 in 10 people):
- Redness at injection site (erythema)
- Hardening of the skin at injection site (induration)
- Bruising at injection site (ecchymosis)
- Diarrhoea
- Nausea
- Loss of appetite
- Fever (≥ 38°C)
- Shivering
- Flu-like symptoms (only reported in individuals 65 years of age and older)

Uncommon (may affect up to 1 in 100 people):
- Vomiting
- Swelling of the glands in the neck, armpit or groin (lymphadenopathy)

In individuals 65 years of age and older, some side effects were less frequent, such as arthralgia, myalgia (common) and fever (uncommon).

Most side effects were mild or moderate and went away within 3 days of appearing.

In addition, the following side effects occurred occasionally during general use of this vaccine or a similar vaccine in elderly individuals 65 years of age and older:
- 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, pain and redness at the injection site (injection site cellulitis-like reaction)
- Extensive swelling of injected limb
- Swelling of the lower legs or hands (peripheral swelling)
- General weakness or lack of energy (asthenia), generally feeling unwell (malaise)
- Muscular weakness
- Pain on the nerve path (neuralgia), unusual feeling of touch, pain, heat and cold (paraesthesia), fits (convulsions), 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), skin redness (erythema), non-specific rash
- Severe skin rash (erythema multiforme)

- Swelling most apparent in the head and neck, including the face, lips, tongue, throat or any other part of the body (angioedema)
- Blood vessel swelling that may cause skin rashes (vasculitis) and temporary kidney problems
- Dizziness
- Fainting, feeling about to faint (syncope, presyncope)

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 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 Seqirus

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

Store in a refrigerator (2 °C to 8 °C). Do not freeze. Discard if the vaccine has been frozen.
Keep the pre-filled syringe in the outer carton in order to protect from light.

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

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 Adjuvanted Trivalent Influenza Vaccine Seqirus contains

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

	per 0.5 ml dose
A/Victoria/4897/2022 (H1N1)pdm09-like strain (A/Victoria/4897/2022, IVR-238)	15 micrograms HA**
A/Croatia/10136RV/2023 (H3N2)-like strain (A/Croatia/10136RV/2023, X-425A)	15 micrograms HA**
B/Austria/1359417/2021-like strain (B/Austria/1359417/2021, BVR-26)	15 micrograms HA**

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

This vaccine complies with the WHO recommendations (Northern Hemisphere) and EU recommendation for the 2025/2026 season.

- MF59C.1 is included in this vaccine as an adjuvant. Adjuvants are substances included in certain vaccines to accelerate, improve and/or prolong the protective effects of the vaccine. MF59C.1 is an adjuvant that contains per 0.5 ml dose: squalene (9.75 mg), polysorbate 80 (1.175 mg), sorbitan trioleate (1.175 mg), sodium citrate (0.66 mg) and citric acid (0.04 mg).

- 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 Seqirus looks like and contents of the pack

Adjuvanted Trivalent Influenza Vaccine Seqirus is a suspension for injection in a pre-filled syringe. It is a milky-white suspension. A single syringe contains 0.5 ml of suspension for injection.

Adjuvanted Trivalent Influenza Vaccine Seqirus is available in packs containing 1 or 10 pre-filled syringes with or without needles.
Not all pack sizes may be marketed.

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This leaflet was last revised in 06/2025.

The following information is intended for healthcare professionals only:

Appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following the administration of the vaccine.

Gently shake before use. After shaking, the normal appearance of the vaccine is a milky white suspension.

The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine.

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.