Package leaflet: Information for the user

Cell-based Trivalent Influenza Vaccine (Surface Antigen, Inactivated) Seqirus suspension for injection in pre-filled syringe
Influenza vaccine, prepared in cell cultures

▼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 Cell-based Trivalent Influenza Vaccine Seqirus is and what it is used for

Cell-based Trivalent Influenza Vaccine Seqirus is a vaccine against flu (influenza). It is prepared in cell cultures, and, therefore, is egg-free.
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.

Cell-based Trivalent Influenza Vaccine Seqirus is used to prevent flu in adults and children from 6 months of age.

The vaccine targets three strains of influenza virus following the recommendations by the World Health Organisation for the 2024/2025 season.

2. What you need to know before you receive Cell-based Trivalent Influenza Vaccine Seqirus

You should not receive Cell-based 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)
- beta-propiolactone, cetyltrimethylammonium bromide, or polysorbate 80, which are trace residues from the manufacturing process.

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

<u>BEFORE receiving the vaccine</u>

- 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 Cell-based 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 Cell-based 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, Cell-based Trivalent Influenza Vaccine Seqirus may not fully protect all persons who are vaccinated.

Other medicines and Cell-based Trivalent Influenza Vaccine Seqirus suspension
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.

Cell-based Trivalent Influenza Vaccine Seqirus may be given at the same time as other vaccines.

Pregnancy and breast-feeding
Pregnancy:
Tell your doctor if you are pregnant, think you may be pregnant or are planning to have a baby. Influenza vaccines may be given in any trimester of pregnancy.

Breast-feeding:
Use of Cell-based Trivalent Influenza Vaccine Seqirus during breast-feeding has not been studied. No effects on breast fed babies are expected. The vaccine may be given during breast-feeding.

Driving and using machines
Cell-based Trivalent Influenza Vaccine Seqirus has no or negligible effect on your ability to drive and use machines.

Cell-based Trivalent Influenza Vaccine Seqirus contains sodium chloride and potassium chloride
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 Cell-based Trivalent Influenza Vaccine Seqirus is given

This vaccine is given to you by your doctor or nurse as an injection into the muscle at the top of the upper arm (deltoid muscle).

Adults and children from 6 months of age:

One dose of 0.5 ml

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.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
The following side effects have been reported during clinical trials and during general use:

Very serious side effects
Tell your doctor immediately or go to the casualty department at your nearest hospital if you experience the following 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)

Serious side effects
Tell your doctor immediately if you experience any of the following side effects – you may need medical attention:

- You feel weak, you have difficulty moving around or you experience numbness or tingling in your limbs. These can be symptoms of Guillain-Barré syndrome (GBS), an autoimmune disease caused by your body's own immune system.
- Extensive swelling of injected limb

Mild side effects
Very common (may affect more than 1 in 10 people):
- Injection site pain, bruising, reddening and hardening or swelling at the site of the injection
- Headache
- Muscle pain
- Tiredness
- Loss of appetite
- Change in eating habits (only reported in children from 6 months to < 6 years)
- Irritability (only reported in children from 6 months to < 6 years)
- Sleepiness (only reported in children 6 months to < 6 years)
- Diarrhoea

Hardening or swelling at the site of the injection, headache, muscle pain, and tiredness were common in the elderly.
Bruising at the site of the injection was common in adults, elderly and children 9 to < 18 years.
Headache was common in the elderly.
Loss of appetite was common in adults, elderly and children 9 to < 18 years.
Diarrhoea was reported as common in adults, elderly and children 6 years of age and older.

Common (may affect up to 1 in 10 people):
- Nausea, vomiting
- Joint pain
- Shivering
- Fever (≥ 38°C)

Vomiting was uncommon in the elderly.
Fever was uncommon in adults and the elderly

Not known (frequency cannot be estimated from the available data):
- Numbness and tingling sensation (paraesthesia)
- Generalised skin reactions including itching, bumps on the skin (pruritis, urticaria) or non-specific rash

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 Cell-based Trivalent Influenza Vaccine Seqirus

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

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

Do not use this vaccine 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 Cell-based Trivalent Influenza Vaccine Seqirus contains

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

  A/Wisconsin/67/2022 (H1N1)pdm09-like strain (A/Georgia/12/2022 CVR-167) 15 micrograms HA**

  A/Massachusetts/18/2022 (H3N2)-like strain (A/Sydney/1304/2022, wild type) 15 micrograms HA**

  B/Austria/1359417/2021-like strain (B/Singapore/WUH4618/2021, wild type) 15 micrograms HA**

  per 0.5 ml dose
  …….
  * propagated in Madin Darby Canine Kidney (MDCK) cells (this is the special cell culture inwhich the influenza virus is grown);
  ** haemagglutinin

This vaccine complies with the World Health Organisation (WHO) recommendation (northern hemisphere) and EU recommendation for the 2024/2025 season.

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

What Cell-based Trivalent Influenza Vaccine Seqirus looks like and contents of the pack

Cell-based Trivalent Influenza Vaccine Seqirus is a suspension for injection in a pre-filled syringe (ready to use syringe).

Cell-based Trivalent Influenza Vaccine Seqirus is a clear to slightly opalescent suspension.

A single syringe contains 0.5 ml of suspension for injection.

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

Marketing Authorisation Holder
Seqirus UK Ltd.
Point, 29 Market Street
Maidenhead SL6 8AA, UK

Manufacturer
Seqirus Vaccines Limited
Gaskill Road, Speke
L24 9GR Liverpool
United Kingdom

This leaflet was last revised in 07/2024

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.

Shake before use. After shaking, the normal appearance of the vaccine is a clear to slightly opalescent 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.