PACKAGE LEAFLET

Package leaflet: information for the user

Adjuvanted Zoonotic Influenza Vaccine
(Surface Antigen, Inactivated) Seqirus suspension for injection in pre-filled syringe
Zoonotic influenza vaccine (H5N8) (surface antigen, inactivated, adjuvanted)

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 nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Adjuvanted Zoonotic Influenza Vaccine Seqirus H5N8 is and what it is used for

Adjuvanted Zoonotic Influenza Vaccine Seqirus H5N8 is a vaccine for use in individuals 6 months of age and older, intended to be given in the context of outbreaks of zoonotic influenza (coming from birds) to prevent flu caused by H5 subtype influenza A viruses.

Zoonotic influenza viruses occasionally infect humans, and can cause disease ranging from mild upper respiratory infection (fever and cough) to rapid progression to severe pneumonia, acute respiratory distress syndrome, shock and even death. Human infections are primarily caused by contact with infected animals, but do not spread easily between people.

Adjuvanted Zoonotic Influenza Vaccine Seqirus H5N8 is intended also to be given when there is anticipation of a possible pandemic due to the same or a similar strain.

When a person is given the vaccine, 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.

2. What you need to know before you receive Adjuvanted Zoonotic Influenza Vaccine Seqirus H5N8

You should not receive Adjuvanted Zoonotic Influenza Vaccine Seqirus H5N8:

if you have previously had a sudden life-threatening allergic reaction to any ingredient of Adjuvanted Zoonotic Influenza Vaccine Seqirus H5N8 (listed in section 6) or to any of the substances that may be present in trace amounts as follows: egg and chicken protein, ovalbumin, formaldehyde, kanamycin and neomycin sulphate (antibiotics), hydrocortisone or cetyltrimethylammonium bromide (CTAB). Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.

Warnings and precautions

Talk to your doctor or nurse before having this vaccine

- if you have had any allergic reaction other than a sudden life-threatening allergic reaction to any ingredient contained in the vaccine, to egg and chicken protein, ovalbumin, formaldehyde, hydrocortisone, kanamycin and neomycin sulphate (antibiotics) or cetyltrimethylammonium bromide (CTAB) (see section 6. Further information).

- if you have a severe infection with a high temperature (over 38°C). If this applies to you then your vaccination will usually be postponed until you are feeling better. A minor infection such as a cold should not be a problem, but your doctor or nurse should advise whether you could still be vaccinated with Adjuvanted Zoonotic Influenza Vaccine Seqirus H5N8.

- if you are having immunosuppressive therapy, e.g. corticosteroid treatment or chemotherapy for cancer, or if you have any condition which makes you prone to infections (immunodeficiency conditions)

- 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.

Adjuvanted Zoonotic Influenza Vaccine Seqirus H5N8 may not fully protect everyone who is vaccinated, especially elderly subjects and those with weakened immune systems, such as HIV patients, or those with underlying long term medical problems, such as diabetes, lung disease or heart problems. Tell your doctor if you have a weak immune system or an underlying long term medical problem.

In any of these cases, TELL YOUR DOCTOR OR NURSE, as vaccination may not be recommended, or may need to be delayed.

Other medicines and Adjuvanted Zoonotic Influenza Vaccine Seqirus H5N8

Tell your doctor or nurse if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription or have recently received any other vaccine.

Adjuvanted Zoonotic Influenza Vaccine Seqirus H5N8 can be given at the same time as non-adjuvanted seasonal influenza vaccines. There is no information on administration of Adjuvanted Zoonotic Influenza Vaccine Seqirus H5N8 with non-influenza vaccines. If administration of Adjuvanted Zoonotic Influenza Vaccine Seqirus H5N8 with other vaccines can not be avoided, the vaccines should be injected into separate limbs. In such cases, you should be aware that the side effects may be more intense.

Children
Vaccination is currently not recommended in children less than 6 months of age.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or nurse for advice before receiving this vaccine. Your doctor needs to assess the benefits and potential risks of giving you the vaccine.

Driving and using machines

Some effects mentioned under section 4. “Possible side effects” may affect the ability to drive or use machines.

Adjuvanted Zoonotic Influenza Vaccine Seqirus H5N8 contains sodium and potassium.

Adjuvanted Zoonotic Influenza Vaccine Seqirus H5N8 contains less than 1 mmol sodium (23 mg) and less than 1 mmol of potassium (39 mg) per 0.5 ml dose, i.e. essentially sodium- and potassium-free.

3. How Adjuvanted Zoonotic Influenza Vaccine Seqirus H5N8 is given

Your doctor or nurse will administer the vaccine in accordance with official recommendations.
A dose (0.5 ml) of the vaccine will be injected into the upper arm (deltoid muscle) or upper thigh, depending on the muscle mass. The vaccine should never be given into a vein.

Two doses of 0.5 ml will be given with an interval of at least 3 weeks.

There is limited experience in elderly over 70 years of age.

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

4. Possible side effects

Like all medicines, Adjuvanted Zoonotic Influenza Vaccine Seqirus H5N8 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 side effect – you may need urgent medical attention or hospitalisation:

- difficulty in breathing, wheezing, swelling of the throat, dizziness, a weak and rapid pulse, decreased blood pressure and skin rash which are symptoms of an anaphylactic reaction (a very severe allergic reaction)

The side effects listed below have occurred with a vaccine similar to Adjuvanted Zoonotic Influenza Vaccine Seqirus H5N8 in clinical studies **in adults**:

Very common (affects more than 1 user in 10):
- At the site of injection: pain/tenderness, hardening of the skin, redness, swelling
- Aching muscles
- Headache
- Fatigue
- Generally feeling unwell
- Shivering

Common (affects 1 to 10 users in 100):
- Aching joints
- Injection site bleeding and bruising
- Fever (uncommon in individuals over 60 years of age)
- Sweating
- Nausea
- Diarrhoea
- Vomiting
- Loss of appetite

Uncommon (affects 1 to 10 users in 1000)
- Hives (urticaria)

These side effects are usually mild and disappear within 3 days without treatment. If they persist, CONSULT YOUR DOCTOR.

The side effects listed below have occurred with a vaccine similar to Adjuvanted Zoonotic Influenza Vaccine Seqirus H5N8 in clinical studies **in children:**

6 months to less than 3 years of age

Very common (affects more than 1 user in 10):
- At the site of injection: tenderness, redness, hardening of the skin, swelling, bruising
- Change in eating habits
- Diarrhoea
- Vomiting
- Sweating and unusual sweating
- Sleepiness
- Iritability
- Unusual crying
- Fever (≥38° C)

Common (affects 1 to 10 users in 100):
- Injection site bleeding
- Shivering

3 years to less than 18 years of age

Very common (affects more than 1 user in 10):
- At the site of injection: pain, redness, hardening of the skin, swelling, bruising
- Headache
- Diarrhoea
- Nausea
- Sweating
- Muscle soreness
- Feeling generally unwell
- Fatigue
- Shivering
- Fever (≥38° C)*

* Reported as common in the 9 to <18 year old population

Common (affects 1 to 10 users in 100):
- Vomiting
- Aching joints
- Loss of appetite

Undesirable effects in **patients with underlying long term medical problems** such as diabetes, lung disease or heart problems and **weakened immune systems** (immunocompromised) such as HIV patients

Very common (affects more than 1 user in 10): Nausea, aching joints, diarrhoea and loss of appetite
Common (affects 1 to 10 users in 100): Vomiting

Other rare side effects observed after routine use:
The additional side effects listed below have occurred in the days or weeks after vaccination with another vaccine similar vaccine. These side effects may occur with Adjuvanted Zoonotic Influenza Vaccine Seqirus H5N8.

- Generalised skin reactions including

- Itching
- Rash or swelling of the skin and mucous membranes
- Angioedema (abnormal swelling of the skin, usually around the eyes, lips, tongue, hands or feet, due to an allergic reaction)

- Disorders of the gut such as abdominal pain

- Neurological disorders such as
  - Severe stabbing or throbbing pain along one or more nerves
  - Tingling
  - Fits
  - Neuritis (inflammation of nerves)
  - Syncope or presyncope (fainting or feeling about to faint)
  - Dizziness, drowsiness

- Swollen lymph nodes, palpitations (irregular or forceful heartbeat), tachycardia (faster than normal heart beat), weakness, pain in the extremities, cough and asthenia (unusual weakness).

In addition, side effects listed below have occurred in the days or weeks after vaccination with adjuvanted and not-adjuvanted vaccines given routinely every year to prevent seasonal flu. These side effects may occur with Adjuvanted Zoonotic Influenza Vaccine Seqirus H5N8.

- Low blood platelet count which can result in bleeding or bruising
- Vasculitis (inflammation of the blood vessels which can cause skin rashes, joint pain and kidney problems)
- Erythema multiforme (type of allergic skin reaction that occurs in response to medications, infections, or illness)
- Neurological disorders such as encephalomyelitis (inflammation of the central nervous system), and a type of paralysis known as Guillain-Barré Syndrome
- Swelling, pain and redness at the injection site (injection site cellulitis-like reaction)
- Extensive swelling of injected limb

Reporting of side effects
If you get any side effects, talk to your doctor 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 Zoonotic Influenza Vaccine Seqirus H5N8

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

Do not use Adjuvanted Zoonotic Influenza Vaccine Seqirus H5N8 after the expiry date which is stated on the carton and the label. The expiry date refers to the last day of that month.

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

Do not throw 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 Zoonotic Influenza Vaccine Seqirus H5N8 contains

- Active Substance:
  Influenza virus surface antigens (haemagglutinin and neuraminidase)* of strain:

  A/Astrakhan/3212/2020 (H5N8)-like strain (CBER-RG8A) (clade 2.3.4.4b) 7.5 micrograms** per 0.5 ml dose

  * propagated in fertilised hens' eggs from healthy chicken flocks
  ** expressed in microgram haemagglutinin.

- Adjuvant MF59C.1:
  The vaccine contains per 0.5 ml 9.75 mg squalene, 1.175 mg polysorbate 80, 1.175 mg sorbitan trioleate.

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

What Adjuvanted Zoonotic Influenza Vaccine Seqirus H5N8 looks like and contents of the pack

Adjuvanted Zoonotic Influenza Vaccine Seqirus H5N8 is a suspension for injection in a pre-filled syringe.

The suspension is a milky-white liquid.

It is provided in a ready-to-use pre-filled syringe, containing a single dose of 0.5 ml for injection.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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

Manufacturer
Seqirus Vaccines Ltd
Gaskill Road, Speke, Liverpool
L24 9GR
UK

Seqirus Netherlands B.V.
Paasheuvelweg 28
1105BJ Amsterdam
Netherlands

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