



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Zoonotic influenza vaccine Seqirus (*zoonotic influenza vaccine [H5N8] [surface antigen, inactivated, adjuvanted]*)

An overview of Zoonotic influenza vaccine Seqirus and why it is authorised in the EU

What is Zoonotic influenza vaccine Seqirus and what is it used for?

Zoonotic influenza vaccine Seqirus is a vaccine used in adults to protect against flu caused by H5 strains of the influenza A virus (also known as avian influenza or bird flu). Bird flu is a zoonotic infection (an infection that can spread from animals to humans).

Zoonotic influenza vaccine Seqirus contains a flu strain called A/Astrakhan/3212/2020 (H5N8)-like strain (CBER-RG8A) (clade 2.3.4.4b) and is based on parts of influenza virus that has been inactivated (killed) so that it does not cause any disease.

How is Zoonotic influenza vaccine Seqirus used?

The vaccine is given as two doses, injected into the shoulder muscle, at least three weeks apart.

Zoonotic influenza vaccine Seqirus can only be obtained with a prescription and should be used according to official recommendations.

For more information about using Zoonotic influenza vaccine Seqirus, see the package leaflet or contact your doctor or pharmacist.

How does Zoonotic influenza vaccine Seqirus work?

Zoonotic influenza vaccine Seqirus works by preparing the immune system (the body's natural defences) to defend itself against bird flu. When a person is given the vaccine, the immune system recognises parts of the virus in the vaccine as 'foreign' and makes antibodies against them. If, later, the vaccinated person comes into contact with the virus, these antibodies, together with other components of the immune system, will be able to kill the virus and help protect against the disease.

Zoonotic influenza vaccine Seqirus contains an adjuvant, a substance that helps strengthen the immune response to the vaccine.

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What benefits of Zoonotic influenza vaccine Seqirus have been shown in studies?

The ability of Zoonotic influenza vaccine Seqirus containing A/Astrakhan/3212/2020 (H5N8)-like strain (CBER-RG8A) (clade 2.3.4.4b) to produce sufficient antibodies to stimulate an immune response and protect against bird flu is based on the following studies.

Two main studies using a strain called A/Vietnam/1194/2004 (H5N1)-like strain (NIBRG-14) (clade 1) provided data on vaccination with Zoonotic influenza vaccine Seqirus in healthy adults aged below and above 60 years.

In one study involving 3,372 people, subjects were given either a seasonal flu vaccine followed by two doses of Zoonotic influenza vaccine Seqirus three weeks apart, or placebo (a dummy vaccine) followed by two doses of an adjuvanted seasonal vaccine three weeks apart. In the first study, 21 days after the second injection, around 90% of people aged below 60 years and around 80% of those aged above 60 years had levels of antibodies that would protect them against H5N1.

In the second study involving 240 people, subjects were given Zoonotic influenza vaccine Seqirus using different vaccination schedules. The studies looked at the ability of the vaccine to trigger the production of antibodies ('immunogenicity') against the flu virus. This study established that Zoonotic influenza vaccine Seqirus should be given as two doses at least three weeks apart.

A third study, using a vaccine with strain A/turkey/Turkey/1/2005 (H5N1)-like strain (NIBRG-23) (clade 2.2.1), was carried out in 343 adults aged below and above 60 years. The study showed that 21 days after the second injection, around 70% of adults below 60 years and around 64% of adults above 60 years achieved an acceptable antibody response.

What are the risks associated with Zoonotic influenza vaccine Seqirus?

For the full list of side effects and restrictions with Zoonotic influenza vaccine Seqirus, see the package leaflet.

The safety of Zoonotic influenza vaccine Seqirus H5N8 is derived from safety data of vaccines containing either the H5N1 turkey/Turkey/1/2005 (NIBRG 23) (clade 2.2.1) or the H5N1 Vietnam/1194/2004 (NIBRG-14) (clade 1) strains.

The most common side effects with Zoonotic influenza vaccine Seqirus (which may affect more than 1 patient in 10) include reactions at the site of injection (swelling, pain, redness and hardening of the skin), myalgia (muscle pain), headache, tiredness, chills and feeling generally unwell.

Zoonotic influenza vaccine Seqirus should not be given to patients who have had an anaphylactic reaction (severe allergic reaction) to any of the components of the vaccine, including those found at trace (very low) levels (egg or chicken protein, ovalbumin [a protein in egg white], kanamycin or neomycin sulphate [antibiotics], formaldehyde, hydrocortisone and cetyltrimethylammonium bromide).

Why is Zoonotic influenza vaccine Seqirus authorised in the EU?

Zoonotic influenza vaccine Seqirus is given before or during a bird flu pandemic to protect against a new strain of influenza A virus. Health experts are concerned that a future bird flu pandemic could be caused by an H5 influenza A strain.

Zoonotic influenza vaccine Seqirus containing the strain H5N8 (clade 2.3.4.4b) was considered to be the best candidate to provide protection against circulating H5 influenza A strains.

The European Medicines Agency therefore decided that Zoonotic influenza vaccine Seqirus's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Zoonotic influenza vaccine Seqirus?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Zoonotic influenza vaccine Seqirus have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Zoonotic influenza vaccine Seqirus are continuously monitored. Suspected side effects reported with Zoonotic influenza vaccine Seqirus are carefully evaluated and any necessary action taken to protect patients.

Other information about Zoonotic influenza vaccine Seqirus

Zoonotic influenza vaccine Seqirus received a marketing authorisation valid throughout the EU on 9 October 2023.

Further information on Zoonotic influenza vaccine Seqirus can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/zoonotic-influenza-vaccine-seqirus.

This overview was last updated in 4-2024.