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Zoonotic influenza vaccine Seqirus (*zoonotic influenza vaccine [H5N1] [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 the H5N1 ('bird flu') strain of the influenza A virus. Zoonotic influenza vaccine Seqirus contains parts of influenza (flu) viruses that have been inactivated.

Zoonotic influenza vaccine Seqirus contains a flu strain called A/turkey/Turkey/1/2005 (H5N1)-like strain (NIBRG-23) (clade 2.2.1).

This medicine is the same as Aflunov, which is already authorised in the EU. The company that makes Aflunov has agreed that its scientific data can be used for Zoonotic influenza vaccine Seqirus ('informed consent').

How is Zoonotic influenza vaccine Seqirus used?

The vaccine is given as two single doses, injected into the muscles of the upper arm, at least three weeks apart. In the event of an officially declared pandemic caused by the H5N1 strain of the influenza A virus, people who have already been vaccinated with Zoonotic influenza vaccine Seqirus (with one or two doses) may be given only one more dose, instead of the two doses recommended for unvaccinated people.

Zoonotic influenza vaccine Seqirus can only be obtained with a prescription and should be used according to official recommendations issued at national level by public health bodies.

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 is given before or during a flu pandemic to protect against a new strain of flu.

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A flu pandemic happens when a new strain of the flu virus has spread because people do not have immunity (protection) against it. Health experts are concerned that a future flu pandemic could be caused by the H5N1 strain of the virus, an infection that can spread from birds to humans (a 'zoonotic' infection).

Vaccines work by preparing the immune system (the body's natural defences) to defend itself against a specific viral disease. This vaccine contains some parts of the H5N1 virus that has first been inactivated (killed) so that it does not cause any disease. 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.

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

Zoonotic influenza vaccine Seqirus has been shown to produce sufficient antibodies to stimulate an immune response and protect against H5N1.

Two main studies using a strain called A/Vietnam/1194/2004 (H5N1)-like strain (NIBRG-14) 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), 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 most common side effects with Zoonotic influenza vaccine Seqirus (which may affect more than 1 patient in 10) include headache, myalgia (muscle pain), reactions at the site of injection (swelling, pain, redness and hardening of the skin), 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).

However, it may be appropriate to give the vaccine to these patients during a pandemic, if facilities for resuscitation are immediately available.

Why is Zoonotic influenza vaccine Seqirus authorised in the EU?

Zoonotic influenza vaccine Seqirus was shown to produce sufficient antibodies to stimulate an immune response and protect against H5N1. 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.

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