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EPAR summary for the public

Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostics

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This is a summary of the European public assessment report (EPAR) for Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostics. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostics.

What is Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostics?

Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostics is a vaccine. It contains parts of influenza (flu) viruses that have been inactivated. Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostics contains a flu strain called A/Vietnam/1194/2004 (H5N1)-like strain (NIBRG-14).

What is Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostics used for?

Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostics is a vaccine for use in adults to protect against flu caused by the H5N1 (“bird flu”) strain of the influenza A virus. The vaccine is given according to official recommendations.

The vaccine can only be obtained with a prescription.

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How is Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostics used?

The vaccine is given by injection into the shoulder muscle in two single doses, at least three weeks apart. In the event of an officially declared pandemic caused by the H5N1 strain of the influenza A, people who have already been vaccinated with Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostics (with one or two doses) may be given only one more dose, instead of the two doses recommended for unvaccinated people.

How does Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostics work?

Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostics is a 'prepandemic' vaccine. This is a type of vaccine to be used to protect against a new strain of flu that may cause a future influenza pandemic. A flu pandemic happens when a new strain of flu virus appears that can spread easily from person to person because people have no immunity (protection) against it. A pandemic can affect most countries and regions around the world. Health experts are concerned that a future flu pandemic could be caused by the H5N1 strain of the virus. The vaccine has been developed to provide protection against this strain, so that it can be used before or during a flu pandemic.

Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. This vaccine contains some parts of the H5N1 virus. The virus has first been inactivated so that it does not cause any disease. When a person is given the vaccine, the immune system recognises the virus parts as 'foreign' and makes antibodies against them. The immune system will then be able to produce antibodies more quickly when it is exposed to the virus again. This may help to protect against the disease caused by the virus.

The vaccine contains an 'adjuvant' (a compound containing oil) to enhance the immune response.

How has Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostics been studied?

The applicant presented data on experimental models with vaccines similar to Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostics.

Two main studies provided data on vaccination with Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostics 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 Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostics three weeks apart, or a placebo (a dummy vaccine) followed by two doses of an adjuvanted seasonal vaccine three weeks apart. In the second study involving 240 people, subjects were given Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostics using different vaccination schedules. The studies looked at the ability of the vaccine to trigger the production of antibodies ('immunogenicity') in line with the CHMP criteria for prepandemic vaccines.

What benefit has Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostics shown during the studies?

According to criteria laid down by the CHMP, a prepandemic vaccine needs to bring about protective levels of antibodies in at least 70% of people for it to be considered suitable. The studies showed that overall Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostics produced an antibody response that met these criteria. 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. The second study established that Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostics should be given as two doses at least three weeks apart.

What is the risk associated with Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostics?

The most common side effects with Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostics (seen in more than 1 patient in 10) are headache, myalgia (muscle pain), reactions at the site of injection (swelling, pain, induration and redness) and fatigue (tiredness). For the full list of all side effects reported with Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostics, see the package leaflet.

Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostics 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) such as egg or chicken protein, ovalbumin (a protein in egg white), kanamycin or neomycin sulphate (antibiotics), formaldehyde and cetyltrimethylammonium bromide. However, it may be appropriate to give the vaccine to these patients during a pandemic, as long as facilities for resuscitation are available.

Why has Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostics been approved?

The CHMP noted that it is likely that a H5N1 strain of the influenza will cause a pandemic in the future. The CHMP decided that Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostics's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostics

The European Commission granted a marketing authorisation valid throughout the European Union for Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostics to Novartis Vaccines and Diagnostics S.r.l. on 29 November 2010. The marketing authorisation is valid for five years, after which it can be renewed.

The full EPAR for Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostics can be searched for on the Agency's website ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about

treatment with Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostics, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 10-2010.