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EPAR summary for the public

Pandemic Influenza Vaccine H5N1 Baxter AG

whole virion influenza virus, propagated in vero cells (continuous cell line of mammalian origin), inactivated, containing antigen of pandemic strain

This is a summary of the European public assessment report (EPAR) for Pandemic Influenza Vaccine H5N1 Baxter AG. 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 Pandemic Influenza Vaccine H5N1 Baxter AG.

What is Pandemic Influenza Vaccine H5N1 Baxter AG?

Pandemic Influenza Vaccine H5N1 Baxter AG is a vaccine that is given by injection. It contains influenza (flu) viruses that have been inactivated (killed). The vaccine contains a flu strain called A/VietNam/1203/2004 (H5N1).

This vaccine is the same as the Celvapan H5N1 mock-up vaccine, which was previously authorised in the European Union (EU). The company that made the Celvapan H5N1 mock-up vaccine has agreed that its scientific data can be used for Pandemic Influenza Vaccine H5N1 Baxter AG ('informed consent').

What is Pandemic Influenza Vaccine H5N1 Baxter AG used for?

Pandemic Influenza Vaccine H5N1 Baxter AG is a vaccine to prevent 'pandemic' flu. It should only be used once a flu pandemic has been officially declared by the World Health Organization or European Union (EU). A flu pandemic happens when a new type (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. The vaccine would be given according to official recommendations.

The vaccine can only be obtained with a prescription.

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How is Pandemic Influenza Vaccine H5N1 Baxter AG used?

Pandemic Influenza Vaccine H5N1 Baxter AG is given by injection into the shoulder muscle or thigh in two doses, at least three weeks apart.

How does Pandemic Influenza Vaccine H5N1 Baxter AG work?

Pandemic Influenza Vaccine H5N1 Baxter AG is a 'mock-up' vaccine. This is a special type of vaccine that is designed to help with the management of a future pandemic.

Before a pandemic starts, nobody knows which strain of flu virus will be involved, so pharmaceutical companies cannot prepare the correct vaccine in advance. Instead, they can prepare a vaccine that contains a strain of flu virus specifically chosen because nobody has been exposed to it, and to which nobody is immune. They can then test this vaccine to see how people react to it, allowing them to predict how people will react when the flu strain causing the pandemic is included.

Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. This vaccine contains a virus called H5N1 that has been inactivated (killed) so that it does not cause any disease. During a pandemic, the virus strain in Pandemic Influenza Vaccine H5N1 Baxter AG will have to be replaced by the strain causing the pandemic before the vaccine can be used.

When a person is given the vaccine, the immune system recognises the inactivated virus as 'foreign' and makes antibodies against it. The immune system will then be able to produce antibodies more quickly when it is exposed to the virus again. This helps to protect against the disease.

The viruses used in Pandemic Influenza Vaccine H5N1 Baxter AG are grown in mammal cells ('vero cells'), unlike those in some other flu vaccines, which are grown in hen's eggs.

How has Pandemic Influenza Vaccine H5N1 Baxter AG been studied?

One main study in adults included 561 healthy volunteers, 281 of whom were over the age of 60 years. The study looked at the ability of two 7.5 microgram doses of the vaccine, given 21 days apart, to trigger the production of antibodies ('immunogenicity').The main measures of effectiveness were the levels of antibodies against the flu virus in the blood before vaccination, on the day of the second injection (day 21), and 21 days after the second vaccination (day 42).

The second main study involved 305 children aged 9 to 17 years, 306 aged 3 to 8 years and 73 aged 6 to 35 months, and also examined the effect of two 7.5 microgram doses of the vaccine 21 days apart. The main measure of effectiveness was the production of protective levels of antibodies 21 days after the second vaccination. The study also looked at the effect of a booster dose given after twelve months in some of the children.

What benefit has Pandemic Influenza Vaccine H5N1 Baxter AG shown during the studies?

According to criteria laid down by the Committee for Medicinal Products for Human Use (CHMP), a mock-up vaccine needs to bring about protective levels of antibodies in at least 70% of adults for it to be considered suitable.

The study showed that Pandemic Influenza Vaccine H5N1 Baxter AG produced an antibody response that met these criteria. At 21 days after the second injection, 72% of the adults below 60 years of age (192 out of 265) and 74% of those above 60 years of age (200 out of 270) had levels of antibodies that would protect them against H5N1. Similarly in children, after the second 7.5-microgram dose, 85% of children aged 9 to 17 years, 73% of those 3 to 8 years, and 69% of those aged 6 to 35 months

had protective levels of antibodies 21 days after the second injection. Although levels of antibodies slowly fell over the year after vaccination, a booster dose after 12 months resulted in protective levels of antibodies in 93 to 100% of children who received it.

What is the risk associated with Pandemic Influenza Vaccine H5N1 Baxter AG?

The most common side effects with Pandemic Influenza Vaccine H5N1 Baxter AG in adults (seen in more than 1 person in 10) are headache, fatigue (tiredness) and pain at the site of the injection. Side effects are similar in children. For the full list of all side effects reported with Pandemic Influenza Vaccine H5N1 Baxter AG, see the package leaflet.

The vaccine must not be given to people who have had an anaphylactic reaction (severe allergic reaction) to any of the components of the vaccine, or to any of the substances found at trace (very low) levels in the vaccine, such as formaldehyde, benzonase or sucrose. If a pandemic has started, however, it may be appropriate to give the vaccine to these patients, as long as facilities for resuscitation are available.

Why has Pandemic Influenza Vaccine H5N1 Baxter AG been approved?

The CHMP decided that Pandemic Influenza Vaccine H5N1 Baxter AG's benefits are greater than its risks in all age groups investigated and recommended that it be given marketing authorisation.

Pandemic Influenza Vaccine H5N1 Baxter AG has been authorised under 'Exceptional Circumstances'. This means that, because the vaccine is a mock up and does not yet contain the strain of flu virus that is causing a pandemic, it has not been possible to obtain full information about the final pandemic vaccine. Every year, the European Medicines Agency (EMA) will review any new information that may become available and this summary will be updated as necessary.

What information is still awaited for Pandemic Influenza Vaccine H5N1 Baxter AG?

When the company that makes Pandemic Influenza Vaccine H5N1 Baxter AG includes the flu strain responsible for a pandemic in the vaccine, it will collect information on the safety and effectiveness of the final pandemic vaccine, and submit this to the CHMP for evaluation.

What measures are being taken to ensure the safe and effective use of Pandemic Influenza Vaccine H5N1 Baxter AG?

A risk management plan has been developed to ensure that Pandemic Influenza Vaccine H5N1 Baxter AG is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Pandemic Influenza Vaccine H5N1 Baxter AG, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Pandemic Influenza Vaccine H5N1 Baxter AG

The European Commission granted a marketing authorisation valid throughout the European Union for Pandemic Influenza Vaccine H5N1 Baxter AG on 16 October 2009.

The full EPAR for Pandemic Influenza Vaccine H5N1 Baxter AG can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more

information about treatment with Pandemic Influenza Vaccine H5N1 Baxter AG, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2013.