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EPAR summary for the public

Pandemic influenza vaccine H5N1 AstraZeneca[1]

pandemic influenza vaccine (H5N1) (live attenuated, nasal)

This is a summary of the European public assessment report (EPAR) for Pandemic influenza vaccine H5N1 AstraZeneca. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Pandemic influenza vaccine H5N1 AstraZeneca.

For practical information about using Pandemic influenza vaccine H5N1 AstraZeneca, patients should read the package leaflet or contact their doctor or pharmacist.

What is Pandemic influenza vaccine H5N1 AstraZeneca and what is it used for?

Pandemic influenza vaccine H5N1 AstraZeneca is a vaccine developed to protect children aged between 12 months and 18 years against influenza (flu) during a flu pandemic.

A flu pandemic occurs when a new strain of flu virus appears that can spread easily because people have no immunity (protection) against it. It can particularly affect children who have not had seasonal flu or received flu vaccines previously. A flu pandemic can affect people worldwide and cause many deaths.

Pandemic influenza vaccine H5N1 AstraZeneca contains live, attenuated (weakened) influenza A virus A/Vietnam/1203/2004 (H5N1) strain.

How is Pandemic influenza vaccine H5N1 AstraZeneca used?

Pandemic influenza vaccine H5N1 AstraZeneca is available as a nasal spray. The dose is one spray (0.1 ml) into each nostril. Two doses of the vaccine are recommended and the child should receive the second dose at least 4 weeks after the first.

[1] Previously known as Pandemic influenza vaccine H5N1 MedImmune

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The vaccine can only be obtained with a prescription. It should be given in an officially declared pandemic and according to official guidance.

How does Pandemic influenza vaccine H5N1 AstraZeneca work?

A vaccine against a specific disease 'teaches' the immune system (the body's natural defences) to defend itself against the disease. Pandemic influenza vaccine H5N1 AstraZeneca is a pandemic preparedness vaccine. This vaccine is intended to help with the management of a future pandemic.

It is not possible to prepare a vaccine for a future pandemic because the strain of the pandemic flu virus is not known in advance. Instead, a pandemic preparedness vaccine can be made to contain a bird flu virus strain that could potentially cause a future pandemic. Most people will not have come into contact with it and therefore will not have built up protection ('immunity') against it. Testing this pandemic preparedness vaccine helps to predict how people will react to the vaccine at the time of a pandemic, when the virus strain in the vaccine will be replaced by a weakened version of the actual strain causing the pandemic.

When a child is given the vaccine, the immune system recognises the weakened virus in the vaccine as foreign and makes antibodies against it. The immune system will then be able to produce antibodies more quickly and in large numbers when it comes into contact with the virus again. This helps to protect against the flu that the virus causes.

What benefits of Pandemic influenza vaccine H5N1 AstraZeneca have been shown in studies?

Because a new pandemic live attenuated vaccine cannot be tested in children, the benefit of this vaccine in children was predicted from studies in adults and from studies of similar live attenuated flu vaccines in children.

Three main studies involving 107 adults found that Pandemic influenza vaccine H5N1 AstraZeneca was able to prepare the immune system to defend itself against the H5N1 virus strain in individuals who had never come into contact with it. Antibodies against this type of vaccine are not easy to measure. However, a second vaccine that acts in a different way is able to make antibodies that can be measured easily. In those who received the second vaccine 3 weeks to 5 years after vaccination with Pandemic influenza vaccine H5N1 AstraZeneca, antibodies increased 4-fold in 73% (8 out of 11) of the individuals compared with 10% of the individuals who had not been previously vaccinated with Pandemic influenza vaccine H5N1 AstraZeneca. This showed that antibodies against Pandemic influenza vaccine H5N1 AstraZeneca increased substantially when vaccinated adults came into contact with the virus again. In addition, there is evidence indicating that the vaccine can protect against different strains of H5N1 virus. The results were similar to those from three other studies involving 170 adults given pandemic preparedness vaccines containing similar types of bird flu virus, such as H7N9 and H7N7, instead of H5N1.

In addition, the company presented extensive supportive data from large studies and from clinical practice on how well other similar pandemic and seasonal live attenuated influenza A vaccines work in children.

Further studies on the effects on the vaccine in children will need to be provided once the the flu strain causing the pandemic is included in the vaccine.

What are the risks associated with Pandemic influenza vaccine H5N1 AstraZeneca?

The most common side effects with Pandemic influenza vaccine H5N1 AstraZeneca (which may affect more than 1 in 10 people) are decreased appetite, headache, runny or stuffy nose, and feeling unwell. For the full list of all side effects reported with Pandemic influenza vaccine H5N1 AstraZeneca, see the package leaflet.

Pandemic influenza vaccine H5N1 AstraZeneca must not generally be given to children who have had a severe allergic reaction to any of the substances in the vaccine including gelatin and gentamicin or to children who have had a severe allergic reaction to eggs or egg proteins, such as ovalbumin. However, in a pandemic, it might be appropriate to give it to children with allergies if facilities for medical treatment of severe allergic reactions are immediately available. For the full list of restrictions, see the package leaflet.

Why is Pandemic influenza vaccine H5N1 AstraZeneca approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) noted that preparing for a potential flu pandemic in children and adolescents meets an important medical need. The vaccine is expected to protect children against pandemic flu, on the basis of data obtained with this vaccine in adults. This is further supported by data in children given similar seasonal and pandemic live attenuated flu vaccines in large studies and in clinical practice. Although Pandemic influenza vaccine H5N1 AstraZeneca might increase wheezing in children aged 1 to 2 years, the risk is considered acceptable in a pandemic situation. Thus, the CHMP decided that the benefits of the medicine in children aged 1 to 18 years are greater than its risks and recommended that it be given marketing authorisation.

Pandemic influenza vaccine H5N1 AstraZeneca has been given 'conditional approval'. This means that there is more evidence to come about the medicine, which the company is required to provide. Every year, the European Medicines Agency will review any new information that becomes available and this summary will be updated as necessary.

What information is still awaited for Pandemic influenza vaccine H5N1 AstraZeneca?

Since Pandemic influenza vaccine H5N1 AstraZeneca has been granted a conditional approval, the company that markets Pandemic influenza vaccine H5N1 AstraZeneca will conduct studies to gather more information on its effectiveness and side effects during its use in a pandemic as well as its shelf life.

What measures are being taken to ensure the safe and effective use of Pandemic influenza vaccine H5N1 AstraZeneca?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Pandemic influenza vaccine H5N1 AstraZeneca have been included in the summary of product characteristics and the package leaflet.

Other information about Pandemic influenza vaccine H5N1 AstraZeneca

The European Commission granted a marketing authorisation valid throughout the European Union for Pandemic influenza vaccine H5N1 MedImmune on 20 May 2016. The name of the medicine was changed to Pandemic influenza vaccine H5N1 AstraZeneca on 24 May 2017.

The full EPAR for Pandemic influenza vaccine H5N1 AstraZeneca can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about prevention of influenza with Pandemic influenza vaccine H5N1 AstraZeneca, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 05-2017.