EMA/95491/2024
EMEA/H/C/006051

Incellipan (*pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted, prepared in cell cultures)*)

An overview of Incellipan and why it is authorised in the EU

What is Incellipan and what is it used for?

Incellipan is a pandemic preparedness vaccine used to protect adults and children against influenza (flu). It can only be used during a pandemic declared officially by the World Health Organization (WHO) or within the European Union (EU). A pandemic occurs when a strain of flu can spread easily from person to person because people have no immunity (protection) against it.

Incellipan contains small amounts of proteins from the influenza virus. The virus has been inactivated so that it does not cause any disease in people who receive the vaccine.

How is Incellipan used?

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

The recommended dose is two injections 3 weeks apart, usually into the muscle of the upper arm. For infants aged 6 to 12 months, the injection is given in the thigh.

For more information about using Incellipan, see the package leaflet or contact your doctor or pharmacist.

How does Incellipan work?

Incellipan is a pandemic preparedness vaccine that contains small amounts of proteins from the flu virus. The vaccine works by preparing the immune system (the body's natural defences) to defend the body against flu. When a person is given the vaccine, the immune system recognises the proteins in the vaccine as 'foreign' and makes antibodies against them. If the person later comes into contact with the virus, these antibodies, together with other components of the immune system, will be able to fight off the virus more effectively and so help to protect the person against the flu. Incellipan also contains an ingredient called an 'adjuvant' which increases the effect of the vaccine by enhancing the immune response.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Incellipan has been developed to help manage a potential flu pandemic. It is not possible to prepare a vaccine for a future flu pandemic because the strain of the virus that will cause the pandemic is not known in advance. Instead, Incellipan was made to contain a flu virus strain that people will not have come into contact with and therefore will not have built up protection (immunity) against it. Incellipan was tested with this strain to gather information about its safety and ability to trigger an immune response. During a pandemic, the virus strain in the vaccine will have to be replaced by the strain causing the pandemic before the vaccine can be used.

What benefits of Incellipan have been shown in studies?

Incellipan is effective at triggering the production of antibodies against the H5N1 subtype of the influenza A virus.

A main study involved around 3,200 adults who received 2 doses of Incellipan or placebo (a dummy vaccine) 3 weeks apart. Three weeks after the second dose, 67% of people who received Incellipan had adequate levels of antibodies against the H5N1 strain in the vaccine, compared with 1% of those who received placebo. Six months after treatment, about 12% of people given Incellipan still had adequate levels of antibodies compared with about 1% of people given placebo.

Another study involved about 330 children aged 6 months to 17 years who were given 2 doses of Incellipan 3 weeks apart. Three weeks after the second dose, about 96% of children given Incellipan had adequate levels of antibodies against the H5N1 strain in the vaccine.

Based on these results the vaccine is expected to offer protection against influenza disease caused by a pandemic influenza strain.

What are the risks associated with Incellipan?

For the full list of side effects and restrictions with Incellipan, see the package leaflet.

The most common side effects with Incellipan in adults and children 6 years or above (which may affect more than 1 in 10 people) include pain at the site of injection, tiredness, headache, feeling generally unwell, muscle pain and joint pain.

Additional very common side effects in children aged 6 years or older (which may affect more than 1 in 10 children) include loss of appetite and nausea.

In children aged 6 months to less than 6 years, the most common side effects (which may affect more than 1 in 10 children) include tenderness at the site of injection, irritability, sleepiness, change in eating habits and fever.

Incellipan must not be used in people allergic to the active substance, any of the other ingredients or the following substances which may be present in the vaccine in trace amounts: beta-propiolactone, cethyltrimethylammonium bromide and polysorbate 80. Incellipan must also not be given to people who have previously had a life-threatening allergic reaction to an influenza vaccine.

Why is Incellipan authorised in the EU?

Incellipan triggers a strong immune response against the H5N1 influenza A virus in adults and children from 6 months of age, although this response wanes over time. This immune response is expected to protect against disease caused by the virus. The vaccine’s side effects are mostly mild to moderate, last a short time, and are similar to those seen with other flu vaccines. Although other pandemic

preparedness vaccines are authorised to protect against influenza viruses during a pandemic, there is a need for additional vaccines to ensure sufficient supplies.

The European Medicine's Agency therefore decided that Incellipan's benefits are greater than its risks and it can be authorised as a pandemic preparedness vaccine in the EU. Incellipan has been given 'conditional authorisation'. This means that it has been authorised on the basis of less comprehensive data than are normally required because it fulfils an unmet medical need in case of a pandemic.

In the event of a pandemic, once the virus strain causing the pandemic has been identified, the manufacturer can include it in the pandemic preparedness vaccine and apply for a 'final' authorisation. A vaccine against the pandemic strain can then be authorised more quickly because the European Medicines Agency has already assessed the vaccine safety and effectiveness with another strain.

Should a flu pandemic occur, the company must provide data on the vaccine's effectiveness and safety against the flu caused by the pandemic strain.

What measures are being taken to ensure the safe and effective use of Incellipan?

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

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

Other information about Incellipan

Incellipan received a conditional marketing authorisation valid throughout the EU on 19 April 2024.

Further information on Incellipan can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/incellipan.

This overview was last updated in 04-2024.