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Celldemic (zoonotic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted, prepared in cell cultures))

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

What is Celldemic and what is it used for?

Celldemic is a vaccine used to protect adults and children from 6 months of age against influenza (flu) caused by the H5N1 subtype of the influenza A virus (sometimes called 'bird flu' or 'avian flu').

Celldemic contains small amounts of proteins from an H5N1 strain of the influenza A virus. The virus has been inactivated so that it does not cause any disease in people who receive the vaccine.

How is Celldemic used?

Celldemic can only be obtained with a prescription and should be used according to official recommendations.

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 Celldemic, see the package leaflet or contact your doctor or pharmacist.

How does Celldemic work?

Celldemic is a vaccine. Vaccines work by preparing the immune system (the body's natural defences) to defend the body against a specific disease. Celldemic contains proteins of a specific strain of the H5N1 flu virus. 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 H5N1 flu. Celldemic also contains an ingredient called an 'adjuvant' which increases the effect of the vaccine by enhancing the immune response.

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What benefits of Celldemic have been shown in studies?

Celldemic is effective at triggering the production of antibodies against the H5N1 strain included in the vaccine.

A main study involved around 3,200 adults who received 2 doses of Celldemic or placebo (a dummy vaccine) 3 weeks apart. Three weeks after the second dose, 67% of people who received Celldemic 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 Celldemic 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 Celldemic 3 weeks apart. Three weeks after the second dose, about 96% of children given Celldemic 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 the H5N1 strain included in the vaccine.

What are the risks associated with Celldemic?

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

The most common side effects with Celldemic 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.

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

Why is Celldemic authorised in the EU?

Celldemic 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, provided the circulating strain is similar to that included in the vaccine. The vaccine's side effects are mostly mild to moderate, last a short time and are similar to those seen with other flu vaccines.

The European Medicines Agency therefore decided that Celldemic'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 Celldemic?

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

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

Other information about Celldemic

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

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

This overview was last updated in 04-2024.