

Prepandemic Influenza Vaccine (H5N1) (Split Virion, Inactivated, Adjuvanted)
GlaxoSmithKline Biologicals
prepandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted)
(A/VietNam/1194/2004 NIBRG-14)

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.

If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Prepandemic Influenza Vaccine (H5N1) (Split Virion, Inactivated, Adjuvanted) GlaxoSmithKline Biologicals?

Prepandemic Influenza Vaccine (H5N1) (Split Virion, Inactivated, Adjuvanted) GlaxoSmithKline Biologicals is a vaccine that is given by injection. It contains parts of influenza (flu) viruses that have been inactivated (killed). The vaccine contains a flu strain called 'A/VietNam/1194/2004 NIBRG-14' (H5N1).

What is the vaccine used for?

Prepandemic Influenza Vaccine (H5N1) (Split Virion, Inactivated, Adjuvanted) GlaxoSmithKline Biologicals is a vaccine for use in adults to protect against flu caused by the H5N1 strain of the influenza A virus. The vaccine is given according to official recommendations. The vaccine can only be obtained with a prescription.

How is the vaccine used?

The vaccine is given by injection into the shoulder muscle in two single doses, at least three weeks apart. Adults over 80 years of age may need a double dose of the vaccine (one injection into each shoulder) with a second double dose three weeks later.

How does the vaccine work?

Prepandemic Influenza Vaccine (H5N1) (Split Virion, Inactivated, Adjuvanted) GlaxoSmithKline Biologicals is a 'prepandemic' vaccine. This is a special type of vaccine that is intended to protect against a strain of flu that may cause a future 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 small amounts of haemagglutinins (proteins from the surface) 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 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 may help to protect against the disease caused by the virus. Before use, the vaccine is made up by mixing together a suspension that contains the virus particles with an emulsion. The resulting 'emulsion' is then injected. The emulsion contains an 'adjuvant' (a compound containing oil) to stimulate a better response.

How has the vaccine been studied?

The main study of the vaccine included 400 healthy adults aged between 18 and 60 years and compared the ability of different doses of the vaccine, with or without the adjuvant, to trigger the production of antibodies ('immunogenicity'). The participants received two injections of the vaccine containing one of four different doses of haemagglutinin. The injections were given 21 days apart. The main measures of effectiveness were the levels of antibodies against the flu virus in the blood at three different times: before vaccination, on the day of the second injection (day 21) and 21 days later (day 42).

A further study looked at the immunogenicity of single or double doses of the vaccine in 437 people aged over 60 years.

What benefit has the vaccine shown during the studies?

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

The main study showed that the vaccine containing 3.75 micrograms of haemagglutinin and the adjuvant produced an antibody response that met these criteria. At 21 days after the second injection, 84% of the people receiving the vaccine had levels of antibodies that would protect them against H5N1.

In elderly people, single doses of this vaccine also met these criteria, except for in the small number of patients aged over 80 years who did not have any protection against the virus at the start of the study. These patients needed double doses of the vaccine for protection.

What is the risk associated with the vaccine?

The most common side effects with Pre-pandemic Influenza Vaccine (H5N1) (Split Virion, Inactivated, Adjuvanted) GlaxoSmithKline Biologicals (seen with more than 1 in 10 doses of the vaccine) are headache, arthralgia (joint pain), myalgia (muscle pain), reactions at the site of the injection (hardening, swelling, pain and redness), fever and fatigue (tiredness). For the full list of all side effects reported with the vaccine, see the Package Leaflet.

The vaccine should 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 very low levels in the vaccine, such as eggs, chicken protein, ovalbumin (a protein in egg white), formaldehyde, gentamicin sulphate (an antibiotic) and sodium deoxycholate. Vaccination should be delayed in people who have a sudden fever.

Why has the vaccine been approved?

The CHMP decided that the benefits of Pre-pandemic Influenza Vaccine (H5N1) (Split Virion, Inactivated, Adjuvanted) GlaxoSmithKline Biologicals are greater than its risks for active immunisation against H5N1 subtype of influenza A virus. The Committee recommended that the vaccine be given marketing authorisation.

Other information about the vaccine:

The European Commission granted a marketing authorisation valid throughout the EU for Pre-pandemic Influenza Vaccine (H5N1) (Split Virion, Inactivated, Adjuvanted) GlaxoSmithKline Biologicals to GlaxoSmithKline Biologicals S.A. on 26 September 2008. This authorisation was based on the authorisation granted to Prepandrix in 2008 ('informed consent').

The full EPAR for the vaccine can be found [here](#).

This summary was last updated in 07-2009.