

**Focetria**  
*pandemic influenza vaccine (surface antigen, inactivated, adjuvanted)*  
*A/California/7/2009 (H1N1)*

**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 for the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).*

**What is Focetria?**

Focetria is a vaccine. It is a suspension for injection that contains parts ('surface antigens') of the influenza (flu) virus. It contains a flu strain called A/California/7/2009 (H1N1)v like strain (X-181).

**What is Focetria used for?**

Focetria is a vaccine to protect against 'pandemic' flu. It should only be used for the influenza A (H1N1) pandemic that was officially declared by the World Health Organization on 11 June 2009. A flu pandemic happens when a new strain of flu virus emerges 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. Focetria is given according to official recommendations. The vaccine can only be obtained with a prescription.

**How is Focetria used?**

Focetria is given as one dose, injected into the upper arm muscle. A second dose may be given after an interval of at least three weeks. This second dose must be given in children aged from 6 months to 8 years of age and in the elderly (over 60 years of age).

**How does Focetria work?**

Focetria is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a 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 helps to protect against the disease.

Focetria contains small amounts of 'surface antigens' (proteins on the outer membrane of the virus that the body recognises as foreign) of a virus called A(H1N1)v that is causing the current pandemic. The virus has been first inactivated so that it does not cause any disease. The outer membranes that contain the surface antigens have then been extracted and purified. The vaccine also contains an 'adjuvant' (a compound containing oil) to enhance the immune response.

**How has Focetria been studied?**

Focetria was first developed as a 'mock-up' vaccine that contained an H5N1 strain of the flu virus called A/Vietnam/1194/2004. The company studied the ability of this mock-up vaccine to trigger the production of antibodies (immunogenicity) against this strain of flu virus in advance of the pandemic. Following the start of the H1N1 pandemic, the company replaced the virus strain in Focetria with the H1N1 strain causing the pandemic, and presented data relating to this change to the Committee for Medicinal Products for Human Use (CHMP).

An ongoing study in 661 healthy adults (including 251 elderly subjects over 60 years of age) is comparing the ability of Focetria H1N1 (as a two-dose schedule) to trigger an immune response with that of experimental vaccines containing either half as much virus material and adjuvant, or twice as much virus material and no adjuvant.

A similar comparative study is also ongoing in 720 healthy children and adolescents (aged between 6 months and 17 years).

**What benefit has Focetria shown during the studies?**

The mock-up vaccine was shown to bring about protective levels of antibodies in at least 70% of people in which it was studied. In line with the criteria laid down by the CHMP, this demonstrated that the vaccine brought about an appropriate level of protection. The CHMP was also satisfied that the change of strain did not affect the characteristics of the vaccine.

In the 132 adult subjects aged between 18 and 60 years who received the marketed formulation of Focetria H1N1, the vaccine was shown after the first dose to trigger immunity to a satisfactory level. The percentage of subjects who had a level of antibodies in their blood that was high enough to neutralise the H1N1 virus (seroprotection rate) was 96%. In 66 children and adolescents aged 9 to 17 years who received the marketed formulation, the seroprotection rate after a first dose was 92%.

**What is the risk associated with Focetria?**

The most common side effects with Focetria (seen in more than 1 patient in 10) are headache, myalgia (muscle pain), reactions at the site of the injection (swelling, pain, hardening and redness), malaise (feeling unwell), sweating, fatigue (tiredness) and shivering. For the full list of all side effects reported with Focetria, see the Package Leaflet.

Focetria should not be given to patients who have had an anaphylactic reaction (severe allergic reaction) to any of the components of the vaccine, or to any substances found at very low levels in the vaccine, such as egg or chicken protein, ovalbumin (a protein in egg white), kanamycin or neomycin sulphate (antibiotics), formaldehyde and cetyltrimethylammonium bromide. However, it may be appropriate to give the vaccine to these patients during a pandemic, as long as facilities for resuscitation are available.

**Why has Focetria been approved?**

The CHMP decided that, based on the information obtained with the mock-up vaccine and the information provided on the strain change, the benefits of Focetria are greater than its risks for the prophylaxis of influenza in the officially declared H1N1 pandemic situation. The Committee recommended that Focetria be given marketing authorisation.

Focetria has been authorised under 'Exceptional Circumstances'. This means that it has not yet been possible to obtain full information about the pandemic vaccine. Every year, the European Medicines Agency will review any new information that may become available and this summary will be updated as necessary.

**What information is still awaited for Focetria?**

The company that makes Focetria will collect information on the safety and effectiveness of the vaccine, and submit this to the CHMP for evaluation.

**Which measures are being taken to ensure the safe use of Focetria?**

The company that makes Focetria will collect information on the safety of the vaccine while it is being used. This will include information on its side effects and its safety in children, the elderly, pregnant women, patients with severe conditions and people who have problems with their immune systems.

**Other information about Focetria:**

The European Commission granted a marketing authorisation valid throughout the European Union for the H5N1 mock-up vaccine for Focetria to Novartis Vaccines and Diagnostics S.r.l. on 2 May 2007. The marketing authorisation for the H1N1 vaccine was granted on 29 September 2009.

The full EPAR for Focetria with the most up-to-date information on how the vaccine can be used can be found [here](#).

**This summary was last updated in 11-2009.**