European Medicines Agency

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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 of 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-179A).

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 in two doses, at least three weeks apart. It is given by injection into the upper arm muscle.

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 stimulate a better response.

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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).

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.

What is the risk associated with Focetria?
The most common side effects with Focetria (seen in between 1 and 10 people in 100) are headache, sweating, arthralgia (joint pain), myalgia (muscle pain), reactions at the site of the injection (redness, swelling, hardening, bruising and pain), fever, malaise (feeling unwell), 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 trace levels in the vaccine, such as egg or chicken protein, ovalbumin (a protein in egg white), kanamycin or neomycin sulphate (antibiotics), formaldehyde, cetyltrimethylammonium bromide and polysorbate 80. 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, 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.

This information was recommended by the CHMP on 24 September 2009. It has been sent to the European Commission for the adoption of a formal decision applicable in all European Union Member States. The full assessment report will be published shortly.

This summary was last updated in 09-2009.