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**EPAR summary for the public**

# Focetria

influenza vaccine (H1N1)v (surface antigen, inactivated, adjuvanted)



This document is a summary of the European Public Assessment Report (EPAR) for Focetria. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Focetria.

## 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)-derived strain NYMC X-181.

## What is Focetria used for?

Focetria is a vaccine to protect against flu caused by the A (H1N1)v 2009 virus. 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 muscle of the shoulder or thigh. A second dose may be given after an interval of at least three weeks. In children aged from six to 35 months of age, the use of a second dose has been shown to increase the immune response. In the elderly (over 60 years of age), the second dose must be given.

## 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. Focetria contains small amounts of 'surface antigens' (proteins

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
**Telephone** +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
**E-mail** info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

on the outer membrane of the virus) of a virus called A(H1N1)v 2009. The virus has been first inactivated (killed) so that it does not cause any disease. The outer membranes that contain the surface antigens have then been extracted and purified.

When a person is given the vaccine, the immune system recognises the virus parts 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.

The vaccine also contains an 'adjuvant' (a compound containing oil) to enhance the immune response.

## How has Focetria been studied?

Focetria was originally developed as a pandemic vaccine, to be used during the influenza A (H1N1) pandemic declared in June 2009. Two main studies have been carried out that looked at the ability of a two-dose schedule of the vaccine to trigger an immune response, one study in 661 healthy adults (including 251 elderly subjects over 60 years of age), and one study in 720 healthy children and adolescents (aged between six months and 17 years).

## What benefit has Focetria shown during the studies?

In both studies, the vaccine was shown to bring about protective levels of antibodies to a satisfactory level, in line with the criteria laid down by the CHMP.

The CHMP noted that a single dose was able to trigger immunity to a satisfactory level in adults and children and adolescents aged six months to 17 years.

## 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 (pain, hardening and redness), malaise (feeling unwell), sweating and fatigue (tiredness). 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 (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.

## Why has Focetria been approved?

The CHMP decided that Focetria's benefits are greater than its risks and recommended that it be given marketing authorisation.

Focetria was originally authorised under 'exceptional circumstances', because, for scientific reasons, limited information was available at the time of approval. As the company had supplied the additional information requested, the 'exceptional circumstances' ended on 12 August 2010.

## Other information about Focetria:

The European Commission granted a marketing authorisation valid throughout the European Union for Focetria to Novartis Vaccines and Diagnostics S.r.l. on 2 May 2007. The marketing authorisation is valid for five years, after which it can be renewed.

The full EPAR for Focetria can be found here. For more information about treatment with Focetria, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 06-2010.