European Medicines Agency
Veterinary Medicines

EMEA/V/C/061

EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

VIRBAGEN OMEGA

EPAR summary for the public

This document is a summary of the European Public Assessment Report. Its purpose is to explain how the assessment done by the Committee for Medicinal Products for Veterinary Use (CVMP) on the basis of the documentation provided, led to the recommendations on the conditions of use. This document cannot replace a face-to-face discussion with your veterinarian. If you need more information about your animal's medical condition or treatment, contact your veterinarian. If you want more information on the basis of the CVMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Virbagen Omega?

Virbagen Omega is a lyophilisate (freeze dried pellet) and solvent that is made into a suspension for injection. Virbagen Omega contains the active substance recombinant omega interferon of feline origin (from cats) at 5 MU/ vial or 10 MU/ vial. It is used for dogs and cats.

What is Virbagen Omega used for?

Virbagen Omega is used to reduce mortality and clinical signs of parvovirosis (a highly contagious viral infection of dogs) in dogs from one month of age.

Virbagen Omega is also used to treat cats infected with FeLV (feline leukaemia virus) and/or FIV (feline immunodeficiency virus), in non-terminal cats from the age of 9 weeks.

Dogs: The suspension should be injected intravenously (into a vein) once daily for 3 consecutive days. The dose is 2.5 MU/kg bodyweight.
Cats: The suspension should be injected subcutaneously (under the skin) once daily for 5 consecutive days. The dose is 1 MU/kg bodyweight. Two further 5-day treatments must be carried out at 14 days, and 60 days after the first 5-day course.

How does Virbagen Omega work?

Virbagen Omega contains the active substance recombinant omega interferon. Interferons are a family of naturally occurring proteins that are produced in response to viral infections. Virbagen Omega works by stimulating the immune system to attack the virus. The active substance of Virbagen Omega, omega interferon, is produced by a method known as 'recombinant technology'. The omega interferon is made by a cell that has received a gene (DNA), which makes it able to produce omega interferon. The replacement omega interferon acts in the same way as naturally produced omega interferon.

How has the effectiveness of Virbagen Omega been studied?

Virbagen Omega has been studied in dogs (males and females) of at least five weeks old that were infected with parvovirosis. Virbagen Omega 2.5 MU/kg was given intravenously for 3 days. The main measure of effectiveness was the mortality rate compared with dogs that had not been treated.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 16
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

Virbagen Omega has also been studied in the treatment of anaemic or non-anaemic cats infected with FeLV and/or FIV, from the age of 9 weeks. The main measure of effectiveness was the mortality rate compared with cats that had not been treated and clinical signs after treatment.

What benefit has Virbagen Omega shown during the studies?

The mortality rate for dogs treated with Virbagen Omega was 4.4-6.4 times lower than that of the untreated animals.

In the treatment of cats with FeLV, there was a reduction of clinical signs over 4 months and a reduction in the mortality rate. In anaemic cats, the mortality rate in cats infected by FeLV (about 60%) was reduced by about 30%. In non-anaemic cats, the mortality rate (50 %) was reduced by 20%. In cats infected by FIV, the mortality rate was low (5%) and was not changed by the treatment. In the population of cats (whether they were FeLV positive, FIV positive or co-infected by both viruses, there was a reduction of clinical signs over time, improving the quality of life of cats.

What is the risk associated with Virbagen Omega?

The injection of Virbagen Omega may cause the following temporary symptoms in dogs and cats:
• hyperthermia (increased temperature, 3-6 hours after injection)
• transitory vomiting
• soft faeces to mild diarrhoea, in cats only
• fatigue during the treatment, in cats only

There may be a slight decrease in white blood cells, platelets and red blood cells, and a rise in the concentration of alanine aminotransferase (a liver enzyme). These symptoms return to normal in the week after the last injection.

What are the precautions for the person who gives the medicine or comes into contact with the animal?

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the doctor.

Why has Virbagen Omega been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) agreed that the benefits of Virbagen Omega are greater than any risks to reduce mortality and clinical signs of parvovirosis in dogs from one month of age, and to treat cats infected with FeLV (feline leukaemia virus) and/or FIV in non-terminal cats from the age of 9 weeks. They recommended that Virbagen Omega should be given a marketing authorisation. The benefit-risk balance may be found in module 6 of this EPAR.

Other information about Virbagen Omega:

The European Commission granted a marketing authorisation valid throughout the European Union, for Virbagen Omega to Virbac SA on 6 November 2001. Information on the prescription status of this product may be found on the labelling.

This summary was last updated in December 2006.