



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/151380/2013  
EMA/V/C/002562

## EPAR summary for the public

---

# Oncept IL-2

## Feline interleukin-2 recombinant canary pox virus

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 Oncept IL-2?

Oncept IL-2 is a veterinary medicine that contains the active substance feline interleukin-2 recombinant canarypox virus (vCP1338). It is available as a lyophilisate (freeze dried pellet) and solvent (water for injections) that are made up into a suspension for injection.

### What is Oncept IL-2 used for?

Oncept IL-2 is used to treat cats with fibrosarcoma, a type of aggressive tumour which affects the soft tissues. It is used in combination with surgery and radiotherapy to reduce the risk of and delay the tumour coming back. Oncept IL-2 is used when the size of the tumour is between 2 and 5 cm in diameter and there is no spread of the cancer to other parts of the body.

Treatment with Oncept IL-2 should begin the day before radiotherapy and preferably within one month of the removal of the tumour by surgery. A course of treatment consists of six doses of 1 ml, the first four given at intervals of one week, and the last two at two-week intervals. Each dose is divided into five injections (of approximately 0.2 ml each) under the skin around the site of the surgically removed tumour.



## **How does Oncept IL-2 work?**

Oncept-IL2 is an immunomodulating agent, which means that it affects the activity of the immune system (the body's natural defences). The active substance in Oncept IL-2 is a 'carrier' canarypox virus that contains the gene to produce the protein feline interleukin-2 (IL-2). IL-2 works by stimulating some of the specialised cells of the immune system to attack the cancer cells. This is expected to kill the cancer cells.

The virus allows the production of IL-2 in small amounts and for a prolonged time at the injection site. Canarypox viruses do not spread or multiply in cats or in mammals. Oncept-IL2 is produced by a method known as 'recombinant DNA technology': it contains viruses that have received a gene (DNA), which makes them able to produce IL-2.

## **How has Oncept IL-2 been studied?**

Oncept IL-2 was studied in two field studies involving 71 cats which had spontaneously developed fibrosarcoma that had not spread to other parts of the body. The two studies compared a total of 48 cats treated with Oncept IL-2 with 23 control cats that just received surgery and radiotherapy. The main measure of effectiveness was the time until the tumours came back or spread (relapse).

## **What benefit has Oncept IL-2 shown during the studies?**

The studies showed that in cats treated with Oncept IL-2 the tumours took longer to come back (over 730 days based on the mid value of the range) compared with control cats (287 days). Oncept IL-2 reduced the risk of relapse in the period from six months after the start of treatment by approximately 56% after one year and 65% after two years.

## **What is the risk associated with Oncept IL-2?**

Side effects that may be seen with Oncept IL-2 treatment are short lived apathy (lack of responsiveness) and hyperthermia (increased body temperature above 39.5 °C from the normal value of 38 – 38.5 °C).

A moderate reaction at the injection site may occur that involves signs of pain when the area is touched, swelling and scratching. It usually disappears spontaneously within one week.

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

If the product is accidentally self-injected, medical advice should be sought immediately and the package leaflet or label shown to the doctor.

## **Why has Oncept IL-2 been approved?**

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Oncept IL-2 exceed the risks for the approved indication and recommended that Oncept IL-2 be given a marketing authorisation. The benefit/risk balance may be found in the scientific discussion module of this EPAR.

## **Other information about Oncept IL-2:**

The European Commission granted a marketing authorisation valid throughout the European Union, for Oncept IL-2 on 3/05/2013. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in March 2013.