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**EPAR summary for the public**

# Semintra

telmisartan

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 Semintra?

Semintra is a veterinary medicine that contains the active substance telmisartan. It is available as a 4 mg/ml oral solution.

## What is Semintra used for?

Semintra is used to reduce proteinuria (protein in the urine). This can occur with chronic (long term) kidney disease in cats, a common disease in elderly cats characterised by a progressive deterioration of kidney function over time.

The recommended dose is 1 mg telmisartan per kg body weight given once a day by mouth using the measuring syringe provided.

## How does Semintra work?

The active substance in Semintra, telmisartan, is an 'angiotensin II receptor antagonist', which means that it blocks the action of a hormone in the body called angiotensin II. Angiotensin II is a powerful vasoconstrictor (a substance that constricts blood vessels). By blocking the receptor to which angiotensin II normally attaches, telmisartan stops the hormone having an effect, allowing the blood vessels to expand. This allows blood pressure to drop with a resulting decrease in protein in the urine which may slow down progression of kidney disease.

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## How has Semintra been studied?

Semintra was compared to benazepril (another medicine used in veterinary medicines to reduce proteinuria) in a field study involving 224 cats, aged mainly over 11 years, with chronic kidney disease. The main measure of effectiveness was the ability to reduce proteinuria.

## What benefit has Semintra shown during the studies?

Semintra was as effective as benazepril in reducing proteinuria in cats with chronic kidney disease. Semintra decreased protein in the urine within the first seven days after the start of treatment.

## What is the risk associated with Semintra?

Mild and transient side effects affecting the gut that occurred rarely (affecting more than 1 but less than 10 animals in 10,000 animals) were (in order of decreasing frequency) mild and intermittent regurgitation, vomiting, diarrhoea or soft faeces. A decrease in blood pressure and red blood cell levels may also be seen.

For a full list of all side effects reported with Semintra, see the package leaflet.

Semintra must not be given to pregnant or lactating cats. It must also not be given to animals that are hypersensitive to telmisartan or any of the other ingredients of the product.

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

If Semintra is swallowed accidentally, medical advice should be sought immediately and the package leaflet or label shown to the doctor. The person administering Semintra should avoid getting it in their eyes. If contact with the eyes occurs they should be rinsed with water. Hands should be washed after giving the medicine. Pregnant women should take special care to avoid contact with the product. People who are hypersensitive to telmisartan or other angiotensin II receptor antagonists should avoid contact with Semintra.

## Why has Semintra been approved?

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

## Other information about Semintra:

The European Commission granted a marketing authorisation valid throughout the European Union, for Semintra on 13 February 2013. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated on 13 February 2013.