



EMA/732937/2010  
EMA/V/C/002233

## EPAR summary for the public

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# Comfortis

## spinosad

This document is a summary of the European Public Assessment Report (EPAR). 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 Comfortis?

Comfortis is a veterinary medicine that contains spinosad. It is available as chewable tablets in five strengths (90 mg, 140 mg, 180 mg, 270 mg, 425 mg) for dogs and cats and in three additional strengths for larger dogs (665 mg, 1040 mg and 1620 mg).

### What is Comfortis used for?

Comfortis is used to treat and prevent flea infestations in dogs and cats. Comfortis can also be used as part of a treatment strategy for flea allergic dermatitis (an allergic reaction to flea bites).

Comfortis is given as a single dose which can be repeated every month. The appropriate strength tablet(s) should be used according to the dog's or cat's weight (the dose differs between dogs and cats).

### How does Comfortis work?

The active substance in Comfortis, spinosad, is an insecticide which works by interfering with certain receptors (nicotinic acetylcholine receptors) in the fleas' nervous system, which results in their subsequent paralysis and death. The medicine starts killing fleas on the dog or cat 30 minutes after giving the tablet(s) and it remains active for up to four weeks.



## How has Comfortis been studied?

Comfortis has been studied in laboratory animals, as well as in dogs or cats that were treated in various veterinary practices and clinics across Europe ("clinical studies").

Laboratory studies were carried out to look at the effectiveness of Comfortis in killing the fleas on dogs and cats with existing flea infestations, and at the speed of killing fleas on the treated animals.

In the clinical studies, Comfortis was compared with a veterinary medicine authorised in the EU for the treatment and prevention of flea infestations (selamectin, a 'spot-on' applied to the skin of the dog or cat). The studies involved dogs and cats of different age groups, genders, breeds and weights. The effectiveness of the product was measured by looking at the number of fleas that were alive at various times after treatment.

## What benefit has Comfortis shown during the studies?

The results of laboratory studies demonstrated that the product was effective at killing the fleas on dogs or cats with existing flea infestations within 24 hours after treatment.

Comparative studies on fed/fasted dogs indicated that Comfortis tablets should be given with a meal to increase the amount of the active substance absorbed by the dog. Similarly Comfortis tablets should be given with a meal or immediately after feeding in cats.

The clinical studies, carried out for between one and three months, showed that Comfortis is as effective as the comparator medicine in the treatment of flea infestations in dogs and cats. The studies also showed that the preventive effect of spinosad against new flea infestations (which results from its residual insecticidal activity) lasts for up to 4 weeks.

Studies also showed that the frequency and severity of flea allergy dermatitis (an allergic reaction to flea bites) is significantly decreased in dogs and cats treated with Comfortis and so its use as part of a treatment strategy for the control of this condition is justified.

## What is the risk associated with Comfortis?

The most common side effect is vomiting, which is mild and transient in most dogs and cats. Other common side effects in cats include diarrhoea and loss of appetite. For a full list of all side effects reported with Comfortis, see the package leaflet.

Comfortis tablets must not be used in dogs or cats aged less than 14 weeks, or in dogs or cats that are hypersensitive (allergic) to spinosad or any of the other ingredients in the tablets.

Comfortis tablets are not recommended for use in dogs weighing less than 1.3 kg or in cats weighing less than 1.2 kg (an accurate dosing of the product in such small dogs or cats is not possible and they may be accidentally overdosed).

Use of Comfortis tablets in dogs or cats which have epilepsy may involve additional risks.

The safety of Comfortis has not been sufficiently established in dogs or cats that are pregnant or breeding (male or female). The safety for suckling puppies or kittens has not been sufficiently established, therefore Comfortis should only be used in breeding, pregnant or lactating dogs or cats if the veterinary surgeon has specifically recommended it.

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

People who give the medicine should wash their hands after handling Comfortis.

Accidental ingestion, including by children, may cause adverse reactions. In case of accidental ingestion, medical advice should be sought immediately and the package leaflet or the label shown to the doctor.

## **Why has Comfortis been approved?**

The CVMP concluded that the benefits of Comfortis outweigh the risks when used for the approved indications and recommended that Comfortis be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

## **Other information about Comfortis:**

The European Commission granted a marketing authorisation valid throughout the European Union, for Comfortis on 11/02/2011. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in September 2013.