

CAUTION

KEEP OUT OF REACH OF CHILDREN
FOR ANIMAL TREATMENT ONLY

Comfortis™ (spinosad)

Chewable Tablets

Active Constituent:

Comfortis Chewable Tablets are available in 140, 270 and 560 mg spinosad strength for oral administration to dogs and cats, and 810 and 1620 mg tablet strength for oral administration to dogs.

Indications:

Comfortis rapidly kills fleas (*Ctenocephalides felis*) and is intended for the treatment, prevention and control of flea infestations and for the control of flea allergy dermatitis in dogs and cats for one month following a single administration. Comfortis Tablets are not recommended for use in puppies or kittens less than 14 weeks of age.

DIRECTIONS FOR USE

Dosage and Administration:

Comfortis is recommended for use in dogs and cats 14 weeks of age or older. Comfortis tablets are given orally, once a month at the recommended minimum dosage of 30 mg/kg body weight for dogs, and 50 mg/kg body weight for cats, as specified in the following table:

Recommended Dosage Schedule:

Body Weight (kg)*		Spinosad Per Tablet (mg)	Tablets Administered per Month
Dogs	Cats		
2.3 - 4.5	1.4 - 2.7	140	One
4.6 - 9	2.8 - 5.4	270	One
9.1 - 18	5.5 - 11.2	560	One
18.1 - 27	N/A	810	One
27.1 - 54	N/A	1620	One

*Dogs over 54 kg and cats over 11.2 kg should be administered the appropriate combination of tablets. Comfortis should be administered with food for maximum effectiveness.

General Instructions:

Comfortis has been demonstrated to rapidly kill fleas (*Ctenocephalides felis*) and as a result will control flea allergy dermatitis in dogs and cats. Treatment with Comfortis may begin at any time of the year, preferably starting one month before fleas become active and continuing monthly through the end of flea season. In areas where fleas are common year-round, monthly treatment with Comfortis should continue the entire year without interruption. As Comfortis is an oral product, there are no restrictions with regards to swimming or washing after treatment. Dogs and cats can be treated while wet and can be exposed to water immediately after treatment. Additionally, there is no requirement to exclude the dog or cat from access to any furniture or home fittings. As the product is inside the treated animal it cannot damage any surfaces or other materials in the home. To minimize likelihood of flea reinfestation, it is important to treat all animals within a household with an approved flea protection product. Where a heavy environmental infestation is present, the concurrent use of a registered environmental control product on areas such as bedding and carpet may facilitate more rapid resolution of the flea infestation. In some animals, Comfortis has been associated with vomiting, most commonly within 48 hours of administration of the first dose. This is most likely caused by a local effect of spinosad on small intestine vomiting receptors, rather than by a central nervous system effect. In some dogs, the incidence of vomiting may decrease with repeat doses. The mechanism for this apparent 'tolerance' has not been determined. If vomiting occurs within an hour of administration, re-dose with another full dose. If a dose is missed, administer Comfortis with food and resume a monthly dosing schedule. In New Zealand, the following adverse reactions have been observed at an uncommon or rare incidence rate following Comfortis use: depression/lethargy, trembling, ataxia, pruritus and seizures, including "star gazing". Please notify your veterinarian should you observe any of these in your animal following product use.

Dogs

Studies conducted have shown that Comfortis starts to kill fleas within 1 hour of oral administration and kills 100% of fleas within 4 hours.

Comfortis is a chewable tablet and is readily consumed by dogs when offered by the owner just prior to feeding. Alternatively, Comfortis may be offered in food or administered orally like other tablet medications.

Cats

Studies conducted have shown that Comfortis has greater than 90% efficacy within 2 hours and kills 100% of fleas within 24 hours of oral administration.

Some cats may accept Comfortis directly or mixed with food. Alternatively, Comfortis may be administered orally like other tablet medications.

Precautions:

Comfortis should not be administered to puppies or kittens less than 14 weeks of age.

Seek veterinary advice regarding use of Comfortis in pregnant and lactating female dogs and in animals with pre-existing epilepsy.

The safe use of Comfortis in breeding male dogs has not been evaluated.

The safe use of Comfortis in breeding, pregnant, lactating female cats or breeding male cats has not been evaluated.

Concurrent use of Comfortis with high off-label doses of ivermectin for parasitic mange or demodicosis has been associated with an increased risk of developing neurological signs typically associated with ivermectin toxicity. Comfortis should not be administered concurrently with high doses of macrocyclic lactones.

In dogs, Comfortis may be used in conjunction with gastrointestinal worm treatments, topical tick treatments and collars, including products containing macrocyclic lactones, used as per label directions. The safety of Comfortis in conjunction with gastrointestinal worm treatments, with topical tick treatments and collars in cats has not been evaluated.

FIRST AID

If poisoning occurs, contact a doctor or contact the National Poisons Centre, phone 0800 POISON (0800 764 766). Additional information is in the Safety Data Sheet.

Storage:

Store below 25°C (Air Conditioning) and protect from light. Store the unused product in the original closed container. Refer to carton for batch and expiry information.

Disposal:

Dispose of empty containers by wrapping with paper and putting in garbage.

Presentation:

1 chewable tablet, 3 chewable tablets or 6 chewable tablets per carton.

Exclusion of Liability

To the extent permitted by legislation, Elanco will not be liable or responsible for any loss, damage or expense where the product is not used as directed.

By law the user must take due care, obtaining expert advice when necessary, to avoid unnecessary pain and distress when using the product other than as directed on the label.

Registered pursuant to the ACVM Act 1997, No A10118.

See www.foodsafety.govt.nz for registration conditions.

Registered to:

Elanco Animal Health

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