



Company Name: ELANCO ANIMAL HEALTH A DIV OF ELI LILLY AUST PTY
Product Name: LTD COMFORTIS (SPINOSAD) 560MG CHEWABLE TABLETS
APVMA Approval No: 62647/108756



Label Name:	COMFORTIS (SPINOSAD) 560MG CHEWABLE TABLETS
-------------	---

Signal Headings:	CAUTION KEEP OUT OF REACH OF CHILDREN FOR ANIMAL TREATMENT ONLY
------------------	---

Constituent Statements:	Each tablet contains 560 mg SPINOSAD
-------------------------	--------------------------------------

Claims:	Comfortis rapidly kills fleas (<i>Ctenocephalides felis</i>) 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. Monthly administration. Give with a meal. Comfortis is not recommended for use in puppies and kittens less than 14 weeks of age.
---------	---

Net Contents:	6 Chewable Tablets 3 Chewable Tablets 1 Chewable Tablet
---------------	---

Directions for Use:	
---------------------	--

Precautions:	Comfortis should not be administered to puppies or kittens less than 14 weeks of age. Seek veterinary advice regarding regarding the 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 demodectic mange 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 significantly in excess of those approved for heartworm prophylaxis. Post-approval experience continues to support the safety of Comfortis when used in conjunction with macrocyclic lactone-containing
--------------	--

	<p>gastrointestinal worm treatments or heartworm preventatives in dogs when used according to label directions.</p> <p>In dogs, Comfortis may be used in conjunction with topical tick treatments and collars used as per label directions.</p> <p>In cats, the safety of Comfortis in conjunction with macrocyclic lactone-containing gastrointestinal worm treatments or heartworm preventatives and with topical tick treatments and collars has not been evaluated.</p>
--	---

Dosage and Administration:	<p>Administer one tablet by mouth, once a month for dogs between 9.1 and 18.0 kg and cats between 5.5 and 11.2 kg.</p> <p>Comfortis should be administered with food for maximum effectiveness.</p> <p>Refer to Page 3 for Recommended Dosage Schedule</p>
----------------------------	--

General Directions:	Refer to Page 4.
---------------------	------------------

First Aid Instructions:	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126.
-------------------------	--

First Aid Warnings:	
---------------------	--

Additional User Safety:	Additional information is in the Safety Data Sheet
-------------------------	--

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

Storage:	Store below 25°C (Air conditioning) and protect from light. Store the unused product in the original closed container.
----------	--

Side effects:	<p>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.</p> <p>In dogs, the incidence of vomiting decreases with repeat doses. The mechanism for this apparent 'tolerance' has not been determined. In cats, the rate of vomiting does not appear to decrease with repeat doses.</p> <p>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. COMFORTIS may also cause diarrhoea and salivation in cats.</p>
---------------	---

Comfortis (Spinosad) 560mg Chewable Tablets

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
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

*Cats over 11.2kg should be administered the appropriate combination of tablets.

Comfortis Chewable Tablets should be administered with food for maximum effectiveness.

In both dogs and cats, spinosad is rapidly absorbed and extensively distributed after oral administration. Because of the longer half-life in cats compared with dogs, the dosing interval must not be decreased to less than monthly in cats.

General Directions:

COMFORTIS has been demonstrated to rapidly kill fleas (*Ctenocephalides felis*) and 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 Chewable Tablets 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 or 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.

Dogs

Studies conducted have shown that Comfortis starts to kill fleas within 30 minutes 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 starts to kill fleas within 30 minutes, with greater than 90% efficacy within 2 hours and 100% within 24 hours.

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