

CAUTION

KEEP OUT OF REACH OF CHILDREN
FOR ANIMAL TREATMENT ONLY

Comfortis® (spinosad)

Chewable Tablets for Dogs 2.3-54 kg and above

Active Constituent:

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

Comfortis Chewable Tablets are flavoured tablets and each tablet contains:

Comfortis (spinosad) Chewable Tablets for Dogs 2.3 - 4.5 kg:

140 mg spinosad

Comfortis (spinosad) Chewable Tablets for Dogs 4.6 - 9 kg:

270 mg spinosad

Comfortis (spinosad) Chewable Tablets for Dogs 9.1 - 18 kg:

560 mg spinosad

Comfortis (spinosad) Chewable Tablets for Dogs 18.1 - 27 kg:

810 mg spinosad

Comfortis (spinosad) Chewable Tablets for Dogs 27.1 - 54 kg:

1620 mg spinosad

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 for one month following a single administration. Comfortis Chewable Tablets are not recommended for use in puppies less than 14 weeks of age.

DIRECTIONS FOR USE

Dosage and Administration:

'Comfortis' tablets are given orally, once a month at the recommended minimum dosage of 30 mg/kg body weight as specified in the following table:

Recommended Dosage Schedule:

| Body Weight* | Spinosad Per Tablet (mg) | Tablets Administered per Month |
|--------------|--------------------------|--------------------------------|
| 2.3 - 4.5 kg | 140 | One |
| 4.6 - 9 kg | 270 | One |
| 9.1 - 18 kg | 560 | One |
| 18.1 - 27 kg | 810 | One |
| 27.1 - 54 kg | 1620 | One |

*Dogs over 54 kg should be administered the appropriate combination of tablets.

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

General Instructions:

'Comfortis' has been demonstrated to rapidly kill fleas (*Ctenocephalides felis*): studies conducted have shown that Comfortis begins to kill fleas within 30 minutes of oral administration and kills 100% of fleas within 4 hours. Because it kills fleas quickly, 'Comfortis' controls flea allergy dermatitis too.

'Comfortis' is a chewable tablet and is readily consumed by dogs when offered by the owner just prior to feeding. Alternatively, Comfortis Chewable Tablets may be offered in food or administered like other tablet medications. Comfortis Chewable Tablets should be administered at monthly intervals.

In some animals, 'Comfortis' has been associated with vomiting, most commonly within 48 hours of administration of the first dose and decreasing in incidence with repeat doses. If vomiting occurs within an hour of administration, re-dose with another full dose. If a dose is missed, administer Comfortis Chewable Tablets with food and resume a monthly dosing schedule.

Treatment with Comfortis Chewable Tablets 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. The dog can be treated while it is wet and can be exposed to water immediately after treatment.

Additionally, there is no requirement to exclude the dog from access to any furniture or home fittings. As the product is inside the dog 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.

Precautions:

Comfortis Chewable Tablets should not be administered to puppies less than 14 weeks of age.

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

The safe use of Comfortis Chewable Tablets in breeding males 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 significantly in excess of those approved for heartworm prophylaxis. Post approval experience continues to support the safety of 'Comfortis' when used concurrently with heartworm preventatives according to label directions.

Contraindications:

There are no known contraindications for the use of Comfortis Chewable Tablets. 'Comfortis' may be safely used in conjunction with topical tick treatments or collars, as well as with gastrointestinal worm or heartworm treatments used as per label directions.

FIRST AID

If poisoning occurs, contact a doctor or contact the Poisons Information Centre: Phone 13 11 26.

Additional information is in the Material 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:

6 tablets per carton

Comfortis is a registered trademark of Eli Lilly and Company.

Exclusion of Liability

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

AUSTRALIA

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