

CAUTION

**KEEP OUT OF REACH OF CHILDREN
READ SAFETY DIRECTIONS BEFORE OPENING OR USING
FOR ANIMAL TREATMENT ONLY**

COMFORTIS™ PLUS

(spinosad + milbemycin oxime)

Chewable Tablets for Dogs 2.3 - 54 kg and above

ACTIVE CONSTITUENTS

COMFORTIS PLUS Chewable Tablets are available in variable strengths of spinosad + milbemycin oxime for oral administration to dogs.

COMFORTIS PLUS Chewable Tablets are flavoured tablets and each tablet contains:

COMFORTIS PLUS (spinosad + milbemycin oxime) Chewable Tablets for Dogs 2.3 - 4.5 kg: 140 mg spinosad and 2.3 mg milbemycin oxime.

COMFORTIS PLUS (spinosad + milbemycin oxime) Chewable Tablets for Dogs 4.6 - 9 kg: 270 mg spinosad and 4.5 mg milbemycin oxime.

COMFORTIS PLUS (spinosad + milbemycin oxime) Chewable Tablets for Dogs 9.1 - 18 kg: 560 mg spinosad and 9.3 mg milbemycin oxime.

COMFORTIS PLUS (spinosad + milbemycin oxime) Chewable Tablets for Dogs 18.1 - 27 kg: 810 mg spinosad and 13.5 mg milbemycin oxime.

COMFORTIS PLUS (spinosad + milbemycin oxime) Chewable Tablets for Dogs 27.1 - 54 kg: 1620 mg spinosad and 27 mg milbemycin oxime.

Indications

COMFORTIS PLUS is indicated for monthly administration for the prevention of heartworm disease (*Dirofilaria immitis*); for the treatment, prevention and control of flea infestations (*Ctenocephalides felis*) and the control of flea allergy dermatitis; for treatment and control of adult hookworm (*Ancylostoma caninum*), roundworm (*Toxocara canis* and *Toxascaris leonina*) and whipworm (*Trichuris vulpis*) infections in dogs and puppies from eight weeks of age, and 2.3 kg body weight or greater. Efficacy against the hookworm *Uncaria stenocephala* has not been established. The parasite that causes heartworm disease (*Dirofilaria immitis*) does not exist in New Zealand.

DIRECTIONS FOR USE

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.

Dosage and administration

COMFORTIS PLUS tablets are given orally, once a month at the recommended minimum dosage of 30 mg/kg body weight spinosad and 0.5 mg/kg milbemycin oxime as specified in the following table:

Recommended Dosage Schedule:

Body Weight	Spinosad Per Tablet (mg)	Milbemycin Oxime Per Tablet (mg)	Tablets Administered
2.3 - 4.5 kg	140	2.3	One
4.6 - 9 kg	270	4.5	One
9.1 - 18 kg	560	9.3	One
18.1 - 27 kg	810	13.5	One
27.1 - 54 kg	1620	27.0	One*

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

COMFORTIS PLUS should be administered with food for maximum effectiveness. COMFORTIS PLUS may be consumed as a treat by dogs when offered by the owner just prior to feeding. Alternatively, COMFORTIS PLUS may be offered in food or administered like other tablet medications, in conjunction with a meal. To ensure that the entire dose is consumed, watch your dog for several minutes following tablet administration. If the entire dose is not consumed, re-dose as soon as possible with the full dose.

General Instructions:

When administered monthly, COMFORTIS PLUS can prevent your dog from suffering from disease caused by infection with three commonly occurring parasite categories:

- Heartworm
- Intestinal worms (roundworm, hookworm and whipworm)
- Fleas

Heartworm disease

Monthly treatment with COMFORTIS PLUS prevents **heartworm disease** from threatening the health of your dog.

- Heartworm infection can make dogs very sick or even prove fatal.
- Dogs become infected with this parasite (*Dirofilaria immitis*) when a mosquito carrying infective juvenile worms takes a blood meal.
- Worms grow and migrate through the body over a number of months and settle in the heart, lungs and nearby blood vessels, potentially leading to organ failure and death.

As with other monthly heartworm preventatives, dogs should be tested for heartworm prior to commencing treatment with COMFORTIS PLUS. When replacing another monthly heartworm preventative product, the first dose of COMFORTIS PLUS must be given within one month of the last dose of the previous monthly medication.

Intestinal worms

COMFORTIS PLUS also treats and controls the most commonly occurring adult **intestinal worm infections** (roundworms, hookworms and whipworms) that, in addition to causing illness in dogs, can also cause infection in humans.

- Intestinal worms can be picked up from the environment, through the mother's milk when suckling as a pup, or contracted *in-utero* prior to birth.
- Intestinal worms may cause clinical signs ranging from diarrhoea (sometimes bloody), vomiting and abdominal discomfort, to anaemia, weight loss or a failure to thrive, lung disease, or in severe cases, potentially fatal intestinal obstruction.

Regular treatment with COMFORTIS PLUS will protect your dog and your family from these parasites.

Flea Infestations

COMFORTIS PLUS can prevent **flea infestations** from becoming established, and quickly removes any fleas that are on your dog at the time of treatment.

- Fleas may cause signs of severe discomfort for dogs, including scratching, chewing, biting and restlessness
- As fleas suck blood, severe infestations may cause anaemia
- Fleas may transmit tapeworm infection to your pet

Spinosad (one of the active ingredients in COMFORTIS PLUS) has been demonstrated to rapidly kill fleas (*Ctenocephalides felis*): studies conducted have shown that spinosad begins to kill fleas within 30 minutes of oral administration and kills 100% of fleas within 4 hours. Because it kills fleas quickly, spinosad controls flea allergy dermatitis too.

Where a heavy environmental infestation of fleas 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.

COMFORTIS PLUS should be administered at monthly intervals, preferably on the same date each month. If a dose is missed and the monthly interval between doses is exceeded by less than 14 days, immediate administration of COMFORTIS PLUS with food and resumption of a monthly dosing schedule will minimise the opportunity for the development of adult heartworms, intestinal worms and reinfestation by fleas. Consult your veterinarian for advice if the inter-dosing interval has exceeded six weeks.

In some animals, COMFORTIS PLUS may be associated with vomiting, 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.

Treatment with COMFORTIS PLUS may begin at any time of the year, preferably starting one month before fleas and/or mosquitoes become active and continuing monthly through the end of flea and mosquito season. In areas where fleas or mosquitoes are common year-round, monthly treatment with COMFORTIS PLUS should continue the entire year without interruption.

To minimize likelihood of flea or worm reinfestation, it is important to treat all animals within a household with an approved parasite protection product.

As COMFORTIS PLUS 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.

Precautions

COMFORTIS PLUS should not be administered to puppies less than 8 weeks of age. Puppies less than 14 weeks of age may experience an increased rate of vomiting.

Seek veterinary advice regarding the use of COMFORTIS PLUS in pregnant and lactating females, and in dogs with pre-existing epilepsy.

The safe use of COMFORTIS PLUS in breeding males has not been evaluated. Concurrent use of COMFORTIS PLUS with high extra-label doses of ivermectin for parasitic mange or demodicosis may be associated with an increased risk of developing neurological signs typically associated with ivermectin toxicity. COMFORTIS PLUS should not be administered concurrently with extra-label high doses of macrocyclic lactones.

The use of COMFORTIS PLUS in dogs suffering from microfilaremia is not recommended. On rare occasions, transient shock-like (hypersensitivity) reactions have been observed in heartworm positive animals carrying a high number of microfilariae at the time of the first treatment with milbemycin oxime. Dogs with an existing adult *D. Immitis* heartworm infection should be treated with an adulticide prior to commencement of COMFORTIS PLUS.

The following adverse events have been recorded following administration of spinosad and milbemycin oxime together: vomiting, pruritus, lethargy and diarrhoea.

Safety Directions

May irritate the eyes. Avoid contact with eyes. Wash hands after use.

First Aid

If poisoning occurs, contact a doctor or Poisons Information Centre: Phone 0800 POISON (0800 764 766).

If in eyes, hold eyes open, flood with water for at least 15 minutes and see a doctor.

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 tablet, 3 tablets or 6 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.

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