Elanco™

Helping veterinarians help pets live longer, healthier lives

Trifexis® (spinosad + milbemycin oxime)

Comfortis® (spinosad)

Reconcile® (fluoxetine hydrochloride)

Assurity® spinetoram

Building on an outstanding legacy in animal health, Elanco Companion Animal Health strives to develop the latest product innovations to enable veterinarians to help pets live longer, healthier, higher-quality lives. To learn more about Elanco's support of the veterinary profession, please visit Elanco booth **504** or visit **elancovet.com**.

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Call 1 (888) 545-5973 for technical support

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Elanco™

You guys are in.
Spread the word.

Trusted and
proven flea control

NOW approved for **cats** and **smaller dogs**

Kills fleas and prevents and **treats flea infestations** on cats ≥ 2 lbs and dogs ≥ 3.3 lbs, 14 weeks and older

- Starts killing fleas within **30 minutes** — before they can lay eggs
- Effective for a **full month**
- Flavored tablets won't interfere with topical dermatological treatments and a quick speed of kill **minimizes the risk of FAD** flare-ups[1]
- Available by **prescription only** — keeps clients returning to your clinic

For more information, visit us online or call your Elanco or distributor representative today.
comfortis.com | **888-545-5973**

Comfortis®
(spinosad)

Important Safety Information

For cats: The most common adverse reaction recorded in clinical trials was vomiting. Other adverse reactions were: lethargy, decreased appetite, weight loss, and diarrhea. Use with caution with concomitant extra-label use of ivermectin.
For dogs: The most common adverse reaction reported is vomiting. Other adverse reactions reported in decreasing order of frequency are: depression/lethargy, decreased appetite, incoordination, diarrhea, itching, trembling, excessive salivation and seizures. Following concomitant extra-label use of ivermectin with Comfortis, some dogs have experienced the following clinical signs: trembling/twitching, salivation/drooling, seizures, ataxia, mydriasis, blindness and disorientation. Post-approval experience continues to support the safety of Comfortis when used concurrently with heartworm preventatives according to label directions. For product label, including complete safety information, visit comfortis.com or see page

[1]D.N. Carlotti, D.E. Jacobs, 2000. Therapy, control and prevention of flea allergy dermatitis in dogs and cats. Vet. Derm. 11, 83-98

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Elanco™

The combination you've been waiting for

Trifexis™
(spinosad+milbemycin oxime)

Proven flea control.
Heartworm disease protection.
Intestinal parasite control.

Trifexis is a monthly, **chewable tablet** for dogs that is approved by the FDA and combines two proven active ingredients. Trifexis prevents **heartworm** disease, kills **fleas** and prevents infestations, and treats and controls intestinal parasite infections (**hookworm, roundworm, whipworm**) in dogs and puppies 8 weeks of age and older and 5 pounds of body weight and greater.

For more information, call 1 (888) 545-5973
or visit **trifexis.com**

Important Safety Information

Serious adverse reactions have been reported following concomitant extra-label use of ivermectin with spinosad alone, one of the components of Trifexis chewable tablets. Treatment with fewer than three monthly doses after the last exposure to mosquitoes may not provide complete heartworm prevention. Prior to administration of Trifexis, dogs should be tested for existing heartworm infection. Use with caution in breeding females. The safe use of Trifexis in breeding males has not been evaluated. Use with caution in dogs with pre-existing epilepsy.

Puppies less than 14 weeks of age may experience a higher rate of vomiting. The most common adverse reactions recorded in clinical trials were vomiting, pruritus, lethargy and diarrhea. If vomiting occurs within an hour after administration, redose with another full dose. For product label, including complete safety information, see page

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Call 1 (888) 545-5973 for technical support

To learn more visit trifexis.com

Sponsor of the Purdue Center for the Human-Animal Bond

Elanco™

COMFORTIS®-Cats (spinosad)

Chewable Tablets

Before using COMFORTIS chewable tablets, please consult the product insert, a summary of which follows:

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

Indications:

COMFORTIS kills fleas and is indicated for the prevention and treatment of flea infestations (*Ctenocephalides felis*), for one month, on cats and kittens 14 weeks of age and older and two pounds of body weight or greater.

Dosage and Administration:

COMFORTIS is given orally once a month, at the minimum dosage of 22.5 mg/lb (50 mg/kg). Administer COMFORTIS with food for maximum effectiveness. If vomiting occurs within an hour of administration, redose with another full dose. If a dose is missed, administer COMFORTIS with food and resume a monthly dosing schedule.

Contraindications:

There are no known contraindications for the use of COMFORTIS.

Warnings:

Not for human use. Keep this and all drugs out of the reach of children.

Precautions:

Use with caution with concomitant extra-label use of ivermectin. The safe use of COMFORTIS in breeding, pregnant, or lactating cats has not been evaluated.

Adverse Reactions:

In a well-controlled US field study, which included a total of 211 cats (139 treated with COMFORTIS and 72 treated with an active topical control once a month for 3 treatments), no serious adverse reactions were attributed to the administration of COMFORTIS. The most frequently reported adverse reaction in cats was vomiting.

Percentage of Cats (%) with Adverse Reactions

	Month 1		Month 2		Month 3	
	COMFORTIS (n=139)	Active Topical Control (n=72)	COMFORTIS (n=135)	Active Topical Control (n=69)	COMFORTIS (n=132)	Active Topical Control (n=67)
Vomiting	14.4	1.4	14.8	1.4	13.6	4.5
Lethargy	3.6	0	0.7	0	1.5	1.5
Anorexia	2.2	0	0.7	0	2.3	1.5
Weight Loss	1.4	0	0	0	3	0
Diarrhea	1.4	1.4	0.7	2.9	2.3	1.5

Over the 3-month (3-dose) study, vomiting occurred on the day of or the day after at least one dose in 28.1% (39/139) of the cats treated with COMFORTIS and in 2.8% (2/72) of the cats treated with the active topical control. Three of the 139 cats treated with COMFORTIS vomited on the day of or the day after all three doses. Two cats that received extra-label topical otic ivermectin on Day -1 of the field study developed lethargy on Day 1 after COMFORTIS administration on Day 0.

For technical assistance or to report an adverse drug experience, call Elanco at 1-888-545-5973. Additional information can be found at www.comfortis.com. For a complete listing of adverse reactions for spinosad reported to the Center for Veterinary Medicine, see Adverse Drug Experience Reports under http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation

Effectiveness:

In a well-controlled laboratory study, COMFORTIS began to kill fleas 30 minutes after administration and demonstrated 98% effectiveness within 4 hours. COMFORTIS kills fleas before they can lay eggs. In a separate well-controlled laboratory study, COMFORTIS demonstrated 100% effectiveness on the first day following treatment and >90% effectiveness on Day 30.

If a severe environmental infestation exists, fleas may persist for a period of time after dose administration due to the emergence of adult fleas from pupae already in the environment. In a field study conducted in households with existing flea infestations, flea count reductions of 97.5% were observed one month after the first treatment and 99.3% after three monthly treatments with COMFORTIS. Cats with pre-existing signs of flea allergy dermatitis showed improvement in erythema, papules, scaling, alopecia, dermatitis/pyodermatitis, and pruritus as a direct result of eliminating the fleas.

Storage Information:

Store at 20 to 25°C (68 to 77°F), excursions permitted between 15 to 30°C (59 to 86°F).

How Supplied:

COMFORTIS is available in four tablet sizes for use in cats: 90, 140, 270 or 560 mg. Each tablet size is available in color-coded packages of 6 tablets.

NADA #141-277, Approved by the FDA

Manufactured for Elanco Animal Health, A Division of Eli Lilly and Company, Indianapolis, IN 46285

EP085610AMA V01-07-2012

COMFORTIS®-Dogs (spinosad)

Chewable Tablets

Before using COMFORTIS chewable tablets, please consult the product insert, a summary of which follows:

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

Indications:

COMFORTIS kills fleas and is indicated for the prevention and treatment of flea infestations (*Ctenocephalides felis*) for one month, on dogs and puppies 14 weeks of age and older and 3.3 pounds of body weight or greater.

Dosage and Administration:

COMFORTIS is given orally once a month, at the recommended minimum dosage of 13.5 mg/lb (30 mg/kg). Administer COMFORTIS with food for maximum effectiveness. If vomiting occurs within an hour of administration, redose with another full dose. If a dose is missed, administer COMFORTIS with food and resume a monthly dosing schedule.

Contraindications:

There are no known contraindications for the use of COMFORTIS.

Warnings:

Not for human use. Keep this and all drugs out of the reach of children.

Serious adverse reactions have been reported following concomitant extra-label use of ivermectin with COMFORTIS (see POST APPROVAL EXPERIENCE).

Precautions:

COMFORTIS is for use in dogs and puppies 14 weeks of age and older.

Use with caution in breeding females and in dogs with pre-existing epilepsy. The safe use of COMFORTIS in breeding males has not been evaluated.

Adverse Reactions:

In a well-controlled US field study, which included a total of 470 dogs (330 dogs treated with COMFORTIS and 140 dogs treated with an active control), no serious adverse reactions were observed with COMFORTIS. All reactions were regarded as mild and did not result in any dog being removed from the study. The most frequently reported adverse reaction in dogs in the COMFORTIS and active control groups was vomiting. The occurrence of vomiting, most commonly within 48 hours after treatment, decreased with repeated doses of COMFORTIS.

Percentage of Dogs (%) with Adverse Reactions

	Month 1		Month 2		Month 3	
	COMFORTIS Chewable Tablets (N=330)	Active Topical Control (N=139[a])	COMFORTIS Chewable Tablets (N=282)	Active Topical Control (N=124)	COMFORTIS Chewable Tablets (N=260)	Active Topical Control (N=125)
Vomiting	12.7	12.2	7.8	3.2	5.8	4.8
Decreased Appetite	9.1	5	2.8	1.6	1.9	0.8
Lethargy	7.6	5	3.5	4	1.2	0.8
Diarrhea	6.7	5	4.3	0.8	1.2	0
Cough	3.9	5	0.4	2.4	0	0
Polydipsia	2.4	1.4	0.7	0	0.4	0
Vocalization	1.8	0	0.4	0	0.4	0
Increased Appetite	1.5	0	0.4	0.8	0.4	0
Erythema	1.5	0	0.4	0	0.4	0
Hyperactivity	1.2	1.4	0	0	0.4	0
Excessive Salivation	1.2	0	0.4	0	0	0

[a] This number (n=139) is less than the total number of dogs in the safety population for the active control group (n=140) because one dog joined the study late and was only dosed at Month 3.

In US and European field studies, no dogs experienced seizures when dosed with COMFORTIS at the therapeutic dose range of 13.5-27.3 mg/lb (30-60 mg/kg), including 4 dogs with pre-existing epilepsy. Four epileptic dogs that received higher than the maximum recommended dose of 27.3 mg/lb (60 mg/kg) experienced at least one seizure within the week following the second dose of COMFORTIS, but no seizures following the first and third doses. The cause of the seizures observed in the field studies could not be determined.

Post Approval Experience (June 2009):

The following adverse reactions are based on post-approval adverse drug event reporting. The adverse reactions are listed in decreasing order of frequency: vomiting, depression/lethargy, anorexia, ataxia, diarrhea, pruritus, trembling, hypersalivation and seizures.

Following concomitant extra-label use of ivermectin with COMFORTIS, some dogs have experienced the following clinical signs: trembling/twitching, salivation/drooling, seizures, ataxia, mydriasis, blindness and disorientation. Post approval experience continues to support the safety of COMFORTIS when used concurrently with heartworm preventatives according to label directions.

For technical assistance or to report an adverse drug experience, call Elanco at 1-888-545-5973. Additional information can be found at www.comfortis.com. For a complete listing of adverse reactions for spinosad reported to the Center for Veterinary Medicine, see Adverse Drug Experience Reports under http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation.

Effectiveness:

In a well-controlled laboratory study, COMFORTIS began to kill fleas 30 minutes after administration and demonstrated 100% effectiveness within 4 hours. COMFORTIS kill fleas before they can lay eggs. If a severe environmental infestation exists, fleas may persist for a period of time after dose administration due to the emergence of adult fleas from pupae already in the environment. In field studies conducted in households with existing flea infestations of varying severity, flea reductions of 98.0% to 99.8% were observed over the course of 3 monthly treatments with COMFORTIS. Dogs with signs of flea allergy dermatitis showed improvement in erythema, papules, scaling, alopecia, dermatitis/pyodermatitis and pruritus as a direct result of eliminating the fleas.

Storage Information:

Store at 20-25°C (68-77°F), excursions permitted between 15 to 30°C (59 to 86°F).

How Supplied:

COMFORTIS is available in six tablet sizes for use in dogs: 90, 140, 270, 560, 810 or 1620 mg. Each tablet size is available in color-coded packages of 6 tablets.

NADA #141-277, Approved by the FDA

Manufactured for Elanco Animal Health, A Division of Eli Lilly and Company, Indianapolis, IN 46285

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TRIFEXIS®

(spinosad + milbemycin oxime)

Chewable Tablets

Before using TRIFEXIS chewable tablets, please consult the product insert, a summary of which follows:

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

Indications:

TRIFEXIS is indicated for the prevention of heartworm disease (*Dirofilaria immitis*). TRIFEXIS kills fleas and is indicated for the prevention and treatment of flea infestations (*Ctenocephalides felis*), and the treatment and control of adult hookworm (*Ancylostoma caninum*), adult roundworm (*Toxocara canis* and *Toxascaris leonina*) and adult whipworm (*Trichuris vulpis*) infections in dogs and puppies 8 weeks of age or older and 5 pounds of body weight or greater.

Contraindications:

There are no known contraindications to the use of TRIFEXIS Chewable Tablets.

Warnings:

Not for human use. Keep this and all drugs out of the reach of children.

Serious adverse reactions have been reported following concomitant extra-label use of ivermectin with spinosad alone, one of the components of TRIFEXIS Chewable Tablets (see **ADVERSE REACTIONS**).

Precautions:

Treatment with fewer than 3 monthly doses after the last exposure to mosquitoes may not provide complete heartworm prevention (see **EFFECTIVENESS**).

Prior to administration of TRIFEXIS, dogs should be tested for existing heartworm infection. At the discretion of the veterinarian, infected dogs should be treated with an adulticide to remove adult heartworms. TRIFEXIS is not effective against adult *Dirofilaria immitis*. While the number of circulating microfilariae may decrease following treatment, TRIFEXIS is not indicated for microfilariae clearance. Mild, transient hypersensitivity reactions manifested as labored respiration, vomiting, salivation and lethargy, have been noted in some dogs treated with milbemycin oxime carrying a high number of circulating microfilariae. These reactions are presumably caused by release of protein from dead or dying microfilariae.

Use with caution in breeding females. The safe use of TRIFEXIS in breeding males has not been evaluated. Use with caution in dogs with pre-existing epilepsy. Puppies less than 14 weeks of age may experience a higher rate of vomiting.

Adverse Reactions:

In a well-controlled US field study, which included a total of 352 dogs (176 treated with TRIFEXIS chewable tablets and 176 treated with an active control), no serious adverse reactions were attributed to administration of TRIFEXIS chewable tablets. All reactions were regarded as mild.

In some cases, dogs vomited after receiving TRIFEXIS. To ensure heartworm prevention, observe your dog for one hour after administration. If vomiting occurs within an hour of administration, redose with another full dose.

Reactions that occurred at an incidence >2% (average monthly rate) within any of the 6 months of observation are presented in the following table:

Average Monthly Rate (%) of Dogs With Adverse Reactions

Adverse Reaction	TRIFEXIS Chewable Tablets[a]	Active Control Tablets[a]
Vomiting	6.13	3.08
Pruritus	4.00	4.91
Lethargy	2.63	1.54
Diarrhea	2.25	1.54

[a]n=176 dogs

In the US field study, one dog administered TRIFEXIS experienced a single mild seizure 2½ hours after receiving the second monthly dose. The dog remained enrolled and received four additional monthly doses after the event and completed the study without further incident.

Following concomitant extra-label use of ivermectin with spinosad alone, a component of TRIFEXIS, some dogs have experienced the following clinical signs: *trembling/twitching, salivation/drooling, seizures, ataxia, mydriasis, blindness and disorientation*. Spinosad alone has been shown to be safe when administered concurrently with heartworm preventatives at label directions.

In US and European field studies, no dogs experienced seizures when dosed with spinosad alone at the therapeutic dose range of 13.5-27.3 mg/lb (30-60 mg/kg), including 4 dogs with pre-existing epilepsy. Four epileptic dogs that received higher than the maximum recommended dose of 27.3 mg/lb (60 mg/kg) experienced at least one seizure within the week following the second dose of spinosad, but no seizures following the first and third doses. The cause of the seizures observed in the field studies could not be determined.

For technical assistance or to report an adverse drug reaction, call 1-888-545-5973. Additional information can be found at www.TRIFEXIS.com.

Post-Approval Experience (March 2012):

The following adverse reactions are based on post-approval adverse drug event reporting. The adverse reactions are listed in decreasing order of frequency: vomiting, depression/lethargy, pruritus, anorexia, diarrhea, trembling/shaking, ataxia, seizures, hypersalivation, and skin reddening.

Effectiveness:

Heartworm Prevention:

In a well-controlled laboratory study, TRIFEXIS was 100% effective against induced heartworm infections when administered for 3 consecutive monthly doses. Two consecutive monthly doses did not provide 100% effectiveness against heartworm infection. In another well-controlled laboratory study, a single dose of TRIFEXIS was 100% effective against induced heartworm infections. In a well-controlled six-month US field study conducted with TRIFEXIS, no dogs were positive for heartworm infection as determined by heartworm antigen testing performed at the end of the study and again three months later.

Flea Treatment and Prevention:

In a well-controlled laboratory study, TRIFEXIS demonstrated 100% effectiveness on the first day following treatment and 100% effectiveness on Day 30. In a well-controlled laboratory study, spinosad, a component of TRIFEXIS, began to kill fleas 30 minutes after administration and demonstrated 100% effectiveness within 4 hours. In field studies conducted in households with existing flea infestations of varying severity, flea reductions of 98.0% to 99.8% were observed over the course of 3 monthly treatments with spinosad alone. Dogs with signs of flea allergy dermatitis showed improvement in erythema, papules, scaling, alopecia, dermatitis/pyodermatitis and pruritus as a direct result of eliminating the fleas.

Treatment and Control of Intestinal Nematode Infections:

In well-controlled laboratory studies, TRIFEXIS was ≥ 90% effective in removing naturally and experimentally induced adult roundworm, whipworm and hookworm infections.

NADA #141-321, Approved by the FDA

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Lilly Corporate Center, Indianapolis, IN 46285

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