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- Single-dose treatment
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- No work for your clients

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(florfenicol, terbinafine, mometasone furoate) Otic Solution



Claro® Otic Solution is approved for the treatment of ear infections in dogs caused by susceptible strains of yeast (Malassezia pachydermatis) and bacteria (Staphylococcus pseudintermedius). CAUTION: Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian. CONTRAINDICATIONS: Claro® should not be used in dogs known or suspected to be allergic to Claro® or any of its ingredients.



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# Complete Coverage

By Allison Morris, Vice-President Member Experience

#### Through our TVC owner driven product com-

mittee, we've been working hard in 2017 to bring in vendor programs that cover every aspect of the veterinary practice, from major drug manufacturers to electricity, to scrubs.

Currently there are 340 vendors we have looked at – whether the company has brought its products and solutions to TVC or a TVC owner has suggested we research. Our goal in the product committee over the next few years is to dig into that list and pick winners from all categories.

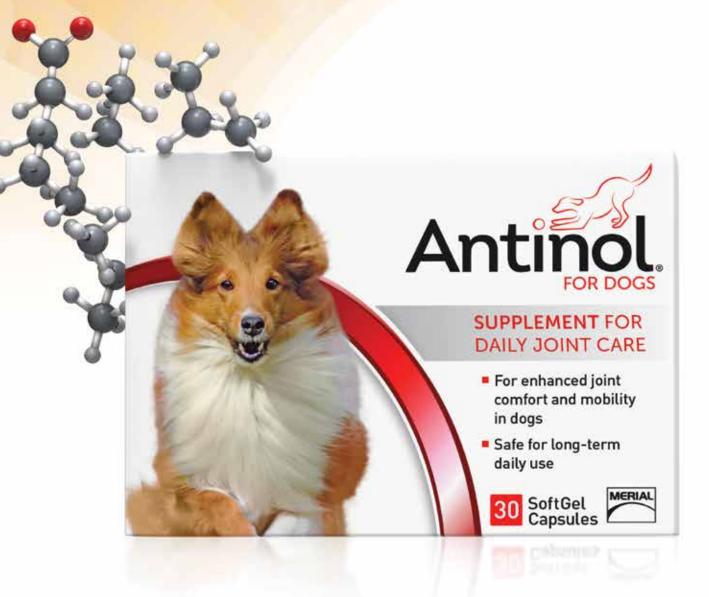
That said, we are bringing in several vendors each quarter, including recently. In July we announced the following vendors:

- VetSource. Through this program we will bring TVC owners a discounted rate using an online pharmacy to better compete against online retailers such as Chewy.com.
- Microsoft. With this program we can help with general computer needs.
- K-Laser. You can purchase from this laser therapy company through your Patterson distributor rep for an extra royalty rebate.
- <u>Technidyne</u>. Offering lift tables, dental operating tables and other types of procedure tables for veterinary clinics – whether your clinic is stationary or mobile. This is a great resource, especially for new clinics starting from scratch, or clinics remodeling.
- Microscope Central. Microscopes aren't something a clinic will purchase
  all the time, but every veterinarian uses one and will need to purchase
  one every so often. We wanted this in our offering so our owners can get a
  nice deal on the purchase. Some microscope purchases can be a sizable
  amount of money.
- <u>DarvalIVet</u> and <u>Vetoquinol</u>. We already have contracts with these vendors, however, they have expanded their product offering with us.

Other vendor programs are in the works. We are working around other equipment focused deals, and other types of services that veterinarians use on a daily or weekly basis. We're hoping to announce more in Q3, and even more in the beginning of 2018, so stay tuned!

Tell us what vendors you would like us to bring on by visiting: <a href="https://theveterinarycooperative.typeform.com/to/QLs5jl">https://theveterinarycooperative.typeform.com/to/QLs5jl</a>

Our goal in the product committee over the next few years is to dig into that list and pick winners from all categories.



#### The power's in the process

ANTINOL's patented process ensures each dose delivers a concentrated blend of EPA, DHA, ETA, and other beneficial fatty acids with their active properties intact<sup>1</sup>

#### Enhances comfort and mobility in dogs:

- In a veterinary assessment, up to 90% of dogs showed enhanced mobility2\*
- In a separate study, dogs showed enhanced mobility within just 2 weeks<sup>3</sup>
- Safe for long-term daily use

Visit www.antinolforpets.com for more information.

\*90% of dogs in one group showed enhanced mobility; 88% of dogs in a second group showed enhanced mobility

**References 1.** Wolyniak CJ, Brenna JT, Murphy KJ, Sinclair AJ. Gas chromatography-chemical ionization-mass spectrometric fatty acid analysis of a commercial supercritical carbon dioxide lipid extract from New Zealand green-lipped mussel (*Perna canaliculus*). *Lipids*. 2005;40(4):355-360. **2.** Data on file. **3.** Data on file.







#### This Month at the Veterinary Cooperative

#### News

Join us at the VMX / NAVC - TVC members enjoy a 10% discount

**More info here** 

#### **TVC and Elanco**

The TVC Board of Directors, along with Rich Morris, Allison Morris, and TVC vendor marketing contacts for Elanco Nick McCart and Judy Avrick, just returned from a 2-day meeting at our vendor partner Elanco's headquarters.

We are pleased to let you know that what developed from meetings and workshops with Elanco sales, marketing, and veterinary stakeholders was a renewed commitment to the partnership between Elanco and TVC and a focus on collaborative efforts to develop relevant programs for independent veterinary clinics.

Elanco is dedicated to the mission and values of The Veterinary Cooperative, and is willing to work with us to bring you programs that will enable you to remain independent in today's increasingly competitive environment.

The TVC Board and TVC staff were divided into groups with the key Elanco stakeholders, and will meet with them over the next 30, 60, 90, and 180 days on a variety of topics to create workable solutions to better serve the needs of the TVC member-owners. We're excited to see what develops!



#### **Promotions**

**Ceva** Adaptil / Feliway - Buy 2 starter kits get 1 free! (more details)

**Elanco** Pet Reach from Elanco. Keep your clients coming back! (more details)

Merial Boehringer Ingelheim- TVC's Largest Promotion EVER! See page 8! (more details)

**Purina** 10% off Select HA and DRM naturals formulas (details here)

**Vetoquinol** Free CE! Feline Herpesvirus pathology, diagnosis and therapy (<u>CE course here</u>)

**VDI** Vitamin D Testing kits - (More info here)





# The New of Ward Ward Breeze of Contract of

**KVP PREMIUM** 

kvpvet.com/premium



#### **Promotions**



#### **Our largest promotion ever, from Boehringer Ingelheim (Merial)**

Until our supply of the ParaVue DX Flea & Tick scanner valued at \$2,500 provided to TVC from BI (formally Merial) runs out, we are excited to be launching our Switch & Save: Flea & Tick campaign supported by Boehringer Ingelheim (formally Merial). As an owner of TVC it is important to remember that the strength of the cooperative stems from its owners. As a co-op, TVC thrives off owner engagement and that is exactly what the Flea & Tick Switch & Save campaign is all about! The more support we get from our owners the more TVC can turn that support into savings that go right back into your pockets. Boehringer Ingelheim also strongly believes that supporting our cooperative is imperative to its continued success and in return, they have teamed up with us to help support any owners who choose to participate.

#### **How Boehringer Ingelheim Supports the Veterinary Cooperative**

From now until September 30, if you choose to Switch & Save away from non-TVC associated vendors and instead make a purchase with any of the following TVC Flea and Tick vendors (See list below) Boehringer Ingelheim will support TVC owners by sending you a ParaVue DX Flea & Tick scanner FREE! (\$2,500 value).

### Boehringer Ingelheim feels very strongly that owners who take an active role in supporting the TVC co-op should be rewarded and in return, Boehringer Ingelheim wants to help by taking an active role in supporting you for your efforts.

<u>Here you</u> will find information regarding the ParaVue DX Flea & Tick scanner. After making a purchase from any of our supported TVC Vendors please visit this link: <u>tvc.coop/to/switch-and-save</u> and fill out THIS form to receive your ParaVue DX Flea & Tick scanner FREE courtesy of Boehringer Ingelheim (Merial).

Supported Switch & Save TVC Vendors:

• Boehringer Ingelheim (formally Merial) • Bayer • Ceva • Elanco

Wedgewood Pharmacy is currently compounding these medications while they are on backorder from their manufacturers. Find pricing, more information and order online in the backorders tab of Order.WedgewoodPetRx.com.

- Amikacin (as Sulfate) 250mg/ml Injection 2ml & 5ml
- Aminopentamide 0.5mg/ml Injection Solution 10ml
- Aminopentamide 0.2mg Tiny Tabs
- Aminophylline 100mg Capsules
- Aminophylline 200mg Capsules

- Ammonium Chloride 400mg Capsules 100ct
- Betamethasone (as Valerate)/Gentamicin (as Sulfate)/Miconazole Nitrate 0.1%/0.15%/1.51% Otic Suspension
- Chloramphenicol 1% 5gm Ophthalmic Ointment



#### Нарру уои. **GOOD THINGS COME IN THREES**

More pet owners would recommend Trifexis to a family member or friend than any other brand.1



#### **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.

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. 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. The most common adverse reactions reported are vomiting, lethargy, pruritus, anorexia and diarrhea. To ensure heartworm prevention, dogs should be observed for one hour after administration. If vomiting occurs within one hour, redose. Puppies less than 14 weeks of age may experience a higher rate of vomiting. For complete safety information, see the product insert at www.Trifexis.com or ask your veterinarian.





#### A little irritation can be a serious problem for

pets and their owners. In the case of one client of TVC Owner Mary Felt, DVM, Dupage Animal Hospital in Villa Park, Ill., it was a persistent ear infection. The pet owner had taken his dog to another veterinarian, who tried different treatments before deciding to perform surgery to open up the ear canal more.

Dr. Felt initially tried out a different food diet for the dog, but to no avail. It wasn't until they conducted allergy testing that they were able to determine what was causing the issue and how to treat it.

"When we finally did the allergy test, we discovered that the dog had no food allergies; it was all environmental. We started immunotherapy treatment, and that dog never had another ear infection in its life."

The biggest thing, Dr. Felt says, was how they were able to help the humananimal bond. "The owner was so happy, and his dog was playful, running around again and back to feeling good."

#### **Impact of allergies**

TVC Owner Sam Morris, DVM, Plum Creek Regional Animal Medical Center in Crete, Ill., says any good generalist can provide allergy testing and treatment for clients. If they refer clients to a dermatologist, they could be missing a significant amount of potential business.

"About half of the patients that come in during allergy season have some form of allergy," Dr. Morris, who is also a TVC Board Member, says. "That's a lot of practice to throw away if I am not treating them."

The symptoms show up in many different ways. Ear infections, skin infections, inflamed eyes, itchiness, sneezing, vomiting, diarrhea, cats with asthma, even allergic bronchitis in dogs. Dr. Felt says she has a handful of dog patients who "like clockwork, will end up with a urinary tract infection every single fall. Or, as soon as the ragweed blooms, they end up with a urinary tract infection."

The challenge is, many things can lead to allergies in pets, including food allergens, environmental, inhal-

ant allergens and more. Because of this, veterinarians need the tools to zero in on exactly what's causing the allergies.

#### **Testing and treatment**

Dr. Felt says they've gotten positive feedback from clients on the <u>Spectrum Labs SPOT testing</u>. It's a simple blood test, but provides comprehensive results to give a more accurate picture of what allergens are affecting the pet. "Clients love it," Dr. Felt says. "Afterwards, whatever the report shows, I can develop a treatment plan from that."

Some dogs have such bad environmental allergies that Dr. Felt says she strongly recommends immunotherapy. Spectrum increases the likelihood for quicker, more lasting relief by including up to 21 allergens in a single treatment set. Treatment for allergies is via subcutaneous injections of the offending allergens. These shots are administered over a 9-month period and administered in increasing doses as well as gradual increases in concentration. The initial 9-month period of hyposensitization is followed by monthly maintenance shots. There is also an oral spray available, specifically made for the allergens the patients are having problems with, for clients who don't want to give their pets injections.

But every single patient with allergies will have something different, Dr. Felt says. "I have a lot of dogs where the allergy is due more to food, so we manage the food and we

can change things from their environment. With probably half of the dogs that get allergy testing, we change so many things at the home and diet that we get their allergies under control. We might have some minor seasonal blowups, but again, we know it's coming, and we know how to handle it and can work through it a lot."

Dr. Morris says having the ability to provide the client with accurate information helps make it easier to get them on board with treatments. After trying several other allergy tests, Plum Creek settled on Spectrum's Spot Platinum 91. "Clients really love the in-depth booklet that comes with the testing. Value-wise, the mix of allergens tested for in the Spot Platinum 91 test is great."



Being able to use an effective product like Spectrum's testing, as well as it coming from a <a href="TVC vendor">TVC vendor</a> "is a win-win ... as well as a win for the patient," Dr. Morris says.

Following the results of the test, Dr. Morris says they schedule a 45-minute sit-down meeting with the clients to go over the booklet and the veterinary practice's plan for managing the allergies going forward. "The pets can come along at this visit. They get lots of love and treats from the staff and doctors, and nothing stressful happens to them. We are sure to emphasize that allergies are life-long, and serious management saves the pet grief and the owners money in the long run rather than continually treating secondary infections. Allergic pets that are uncontrolled are often itchy, smelly and miserable with bacterial infections and chronic otitis. Every time an owner pushes their stinky

#### **Specialty testing**

Allergies are just one area where clients can see the benefits of specialty testing. Another TVC Vendor, VDI Laboratory, offers comprehensive diagnostic testing on a wide range of conditions, including:

#### **Canine**

- Detection & therapeutic management of cancer in dogs with suspected or confirmed cancer
- Diagnostic assessment of hyper/hypo calcemia
- Detection and therapeutic management of critical infections (sepsis)
- Screen test to detect occult disease and assess cancer risk

Determination and monitoring of vitamin D (25D) levels Objective determination of systemic inflammation

#### **Feline**

- Differential diagnosis of GI lymphoma and inflammatory bowel disease
- Diagnostic assessment of hyper/hypo calcemia
- Determination and monitoring of vitamin D (25D) levels

(For a full list of tests offered by VDI, visit <a href="http://vdilab.com/index.php">http://vdilab.com/index.php</a>)

#### **Give your clients options**

TVC Owner Laszlo Frics, DVM ,West Main Animal Hospital, Alhambra, Calif., says that the more tests you can offer, the better you'll be able to help your customers. "Not everybody is going to want a test for everything, but if there is a condition out there, why not test for it and treat it?"

That includes Vitamin D testing. VDI offers a Vitamin D Test Kit that greatly simplifies collection and transportation of specimens for 25 hydroxy-vitamin D testing. Using Spot Saver Card technology, the new test kit requires no refrigeration, no special handling, and no shipping charge. About 80 percent of animals are low on Vitamin D, so practices can test for any deficiencies and then offer medication. "There is a wide open market of pets that could use [Vitamin D testing]," says Dr. Frics.



pet away or yells at them to stop the scratching breaks that pet's heart."

Morris has seen the positive results firsthand with her daughter's dog Chevy, a Golden Retriever. "I can say from seeing the improvement in my daughter's dog that diet change, known allergen avoidance when possible and the treatment kits work. Chevy was an allergic mess by 10 months old and now doesn't smell, has no hot spots and only rarely gets otitis."

#### **Human-animal bond**

Dr. Felt says client knowledge of the benefits of allergy testing is becoming more prevalent, to the point where some ask her about it before she even has a chance to bring it up. "The one client whose dog had the ear surgery, he's owned four dogs, and all four have had allergy tests, even though two never showed clinical signs. He just wanted to know if there could be allergies in the future or what foods to avoid because he saw the difference it made with his other dog."

Dr. Morris says keeping their allergy patients in-house and happy strengthens their bond with the pet and pet parent in a way that benefits everyone. "There are so many pathways available to us to choose in treating allergies that it is important for us to follow these patients rather than us just being gatekeepers for dermatologists," she says. "As generalists, we can figure this out."



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PRESCRIPTION DIET®

- Single, novel protein
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or ask your Hill's Sales Representative how we can help

"Loeffler A, Lloyd DH, Bond R, et al. Dietary trials with a commercial chicken hydrolysate diet in 63 pruritic dogs. Vet Rec. 2004;154:519-522.

<sup>2</sup>Fritsch DA, MacLeay JM. Clinical study to evaluate the efficacy of Prescription Diet z/d Canine in the management of dogs with chronic diarrhea. Data on file.

<sup>3</sup>Hill's Prescription Diet\* z/d\* Canine dry vs. Royal Canin Veterinary Diet\* Hydrolyzed Protein™ Adult HP Canine dry May 2016.

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# How Practices Can Prepare for the Millennial Invasion

By Wendy S. Myers, CVJ

#### Millennials are now the primary pet-owning demographic at 35 percent

of U.S. pet owners compared to Baby Boomers' 32 percent, the American Pet Products Association reports.<sup>1</sup> Millennials spend more on veterinary care and pet services compared to other generations.<sup>2</sup> This generation will add 2.6 million pet owners between now and 2020.<sup>3</sup>

Here are three facts about millennials and how practices need to prepare:

1. Millennials check their smartphones 43 times per day.<sup>4</sup> Be mobile-friendly. Millennials have the highest mobile usage of all generations, with 97% using mobile devices to consume digital content.<sup>5</sup> Veterinary hospitals' websites must be easy to navigate on smartphones and tablets. Millennials are used to researching, ordering and booking on mobile devices.



#### 2. Text is the preferred communication method of millennials.<sup>6</sup>

Look at your smartphone and see who texts you – friends, family, co-workers and people who you know and trust. Veterinary hospitals need to be part of this inner circle, too. Texts have a 99 percent open rate and 95 percent of messages get read within 3 minutes of being sent.<sup>6</sup>

Hospitals must graduate beyond texts for appointment con-

firmations and dosing reminders. Use direct and automated texts for:

- Medication refill requests
- Prescriptions and diets ready for pickup
- Left you voicemail, please listen and call <employee name> at 555-555-5555
- Late arriving clients
- Get clients who missed appointments to reschedule
- Driving directions to new clients on day of first appointment
- · How-to video links
- Weather closure
- · Client experience survey
- Extended hours now available/coming soon
- Lab results ready, please call
- Collections

My veterinarian, The Cat Specialist in Castle Rock, Colo., uses text services from Dialog Health (<a href="www.dialoghealth.com/animalhealth">www.dialoghealth.com/animalhealth</a>). I sent a text to request a refill on my cat's heart medication. The same day, I received a text notice that it was ready for pickup. A text that took less than 10 seconds replaced a 5-minute phone call. I loved the client experience and the hospital team saved time.

#### Millennials love perks, with 77% participating in loyalty reward programs.<sup>7</sup>

Loyalty programs can make clients feel appreciated, improve compliance for patient care and grow clinic revenue. Here are types of loyalty programs:

- Punch card: Stamps or punches are earned and rewards are granted when the card is full. My nail salon has a punch card that gives me a \$15 credit toward services once 10 punches are completed. Employees know my name and encourage me to forward book.
- **Points:** Users accrue points that may be redeemed for cash back or free items. At Starbucks, you earn

points for each coffee purchase and redeem points for free coffee. An app tracks rewards.

 Membership: These pay-to-play programs charge a fee to participate. Rewards are VIP services such as Amazon Prime's free shipping.

Animal Clinic Del Rancho in Scottsdale, Arizona, rewards clients through its free app (<a href="http://animalclinicdelrancho.com/our-app-and-loyalty-program/">http://animalclinicdelrancho.com/our-app-and-loyalty-program/</a>). For every \$100 spent, clients get a digital stamp, with 16 stamps earning a \$100 credit towards a future visit. Rewards never expire.

Companies offering veterinary client loyalty programs include:

- MBF Loyalty, <u>www.mbfloyalty.com</u>
- My Vet Perks, www.myvetperks.com
- Rethink Veterinary Solutions, http://rethinkvetsolutions.com
- Older practice owners can't afford to ignore millennials. They must embrace new technology and marketing strategies for millennials.

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Wendy S. Myers owns Communication Solutions for Veterinarians in Castle Pines, Colo. She helps teams improve client service, communication skills and compliance through consulting, seminars and monthly CE credit webinars. Wendy is a certified veterinary journalist and author of 101 Communication Skills for Veterinary Teams. She offers training packages for receptionists and entire teams. You can reach her at wmyers@csvets.com or www.csvets.com.



## **Industry** NEWS

#### Two more pet food makers won't sell through Chewy

According to a Pet Age report, immediately after pet store giant PetSmart announced it had agreed to acquire Chewy.com in April, Tuffy's Pet Foods stopped offering its products on the online pet retailer's website. Now, two more heavy hitters in the pet food category are joining Tuffy's. Fromm Family Foods and Champion Petfoods have informed independent retailers who carry their foods and treats that they are choosing to pull their products from Chewy.com.

#### Michael J. Fox to keynote VMX 2018

NAVC announced that on Saturday, February 3 at VMX 2018, all VMX registrants are invited to attend the Opening Session featuring Award-Winning Actor & Parkinson's Disease Advocate, Michael J. Fox. Take an inspiring journey through the renowned actor, author and activist's life experiences as he makes the case that real learning and growth actually happens when life goes skidding sideways. He'll share how "A Funny Thing Happened on the Way to the Future" with his characteristic wit and charm. Learn more <a href="here.">here.</a>

#### AVMA Board endorses new recommendations for feline spay/neuter surgery

The AVMA Board of Directors has endorsed a document recommending that cats not intended for breeding be gonadectomized prior to five months of age, according to a blog on the AVMA's website. The Veterinary Task Force on Feline Sterilization Recommendations for Age of Spay and Neuter Surgery is a consensus document put forth by the Veterinary Task Force on Feline Sterilization for Age of Spay and Neuter Surgery. In addition to the AVMA, it also has been endorsed by the American Association of Feline Practitioners, Association of Shelter Veterinarians, American Animal Hospital Association, Winn Foundation, Catalyst Council, Cat Fancier's Association, and The International Cat Association. This document represents a clear and evidence-based position that promotes individual animal health and welfare, contributes to effective population control, and can be communicated clearly to clients. Read more at: <a href="http://atwork.avma.org/2017/07/10/new-recommendations-for-feline-spayneuter-surgery/">http://atwork.avma.org/2017/07/10/new-recommendations-for-feline-spayneuter-surgery/</a>



#### (florfenicol, terbinafine, mometasone furoate)

Antibacterial, antifungal, and anti-inflammatory For Otic Use in Dogs Only

The following information is a summary of the complete product information and is not comprehensive. Please refer to the approved product label for complete product information prior to use.

**CAUTION:** Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.

PRODUCT DESCRIPTION: CLARO® contains 16.6 mg/mL florfenicol, 14.8 mg/mL terbinafine (equivalent to 16.6 mg/mL terbinafine hydrochloride) and 2.2 mg/mL mometasone furoate. Inactive ingredients include purified water, propylene carbonate, propylene glycol, ethyl alcohol, and polyethylene glycol.

#### INDICATIONS:

CLARO® is indicated for the treatment of otitis externa in dogs associated with susceptible strains of yeast (Malassezia pachydermatis) and bacteria (Staphylococcus pseudintermedius).

#### DOSAGE AND ADMINISTRATION:

CLARO" should be administered by veterinary personnel. Administration is one dose (1 dropperettle) per affected ear. The duration of effect should last 30 days. Clean and dry the external ear canal before administering the product. Verify the tympanic membrane is intact prior to administration. Cleaning the ear after dosing may affect product effectiveness. Refer to product label for complete directions for use.

#### CONTRAINDICATIONS:

Do not use in dogs with known tympanic membrane perforation (see **PRECAUTIONS**).

CLARO® is contraindicated in dogs with known or suspected hypersensitivity to florfenicol, terbinafine hydrochloride, or mometasone furoate, the inactive ingredients listed above, or similar drugs, or any ingredient in these medicines.

#### WARNINGS:

<u>Human Warnings</u>: Not for use in humans. Keep this and all drugs out of reach of children. In case of accidental Ingestion by humans, contact a physician immediately. In case of accidental skin contact, wash area thoroughly with water. Avoid contact with eyes. Humans with known hypersensitivity to florfenicol, terbinafine hydrochloride, or mometasone furoate should not handle this product.

#### PRECAUTIONS:

Do not administer orally

The use of CLARO® in dogs with perforated tympanic membranes has not been evaluated. The integrity of the tympanic membrane should be confirmed before administering the product. Revaluate the dog if hearing loss or signs of vestibular dysfunction are observed during treatment.

Use of topical otic corticosteroids has been associated with adrenocortical suppression and iatrogenic hyperadrenocorticism in dogs.

Use with caution in dogs with impaired hepatic function. The safe use of CLARO\* in dogs used for breeding purposes, during pregnancy, or in lactating bitches has not been evaluated.

#### ADVERSE REACTIONS:

In a field study conducted in the United States, there were no directly attributable adverse reactions in 146 dogs administered CLARO®. To report suspected adverse drug events and/or obtain a copy of the Safety Data Sheet (SDS) of for technical assistance, contact Bayer HealthCare at 1-800-422-9874.

For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at http://www.fda.gov/AnimalVeterinary/SafetyHealth.

NADA 141-440, Approved by FDA.

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Bayer



#### Chewable Tablets

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

#### Description:

TRIFEXIS (spinosad and milbemycin oxime) is available in five sizes for oral administration to dogs and puppies according to their weight. Each chewable flavored tablet is formulated to provide a minimum spinosad dose of 13.5 mg/lb (30 mg/kg) and a minimum milbemycin oxime dose of 0.2 mg/lb (0.5 mg/kg). Spinosad is a member of the spinosyns class of insecticides, which are non-antibacterial tetracyclic macrolides. Spinosad contains two major factors, spinosyn A and spinosyn D, derived from the naturally occurring bacterium, Saccharopolyspora spinosa. Spinosyn A and spinosyn D have the chemical compositions  $C_{41}H_{65}NO_{10}$  and  $C_{42}H_{67}NO_{10}$ , respectively. Milbemycin oxime is a macrocyclic lactone anthelmintic, containing two major factors,  $A_3$  and  $A_4$  of milbemycin oxime. The approximate ratio of  $A_3$ : $A_4$  is 20:80. Milbemycin  $A_4$  5-oxime has the chemical composition of  $C_{32}$ : $H_{45}$ NO $_7$  and milbemycin  $A_3$ 5-oxime has the chemical composition of C<sub>31</sub>H<sub>43</sub>NO<sub>7</sub>.

#### 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

#### Dosage and Administration:

TRIFEXIS is given orally, once a month at the minimum dosage of 13.5 mg/lb (30 mg/kg) spinosad and 0.2 mg/lb (0.5 mg/kg) milbemycin oxime body weight. For heartworm prevention, give once monthly for at least 3 months after exposure to mosquitoes (see **EFFECTIVENESS**).

Dosage Deliculie.			
Body Weight	Spinosad Per Tablet (mg)	Milbemycin oxime Per Tablet (mg)	Tablets Administered
5 to 10 lbs	140	2.3	One
10.1 to 20 lbs	270	4.5	One
20.1 to 40 lbs	560	9.3	One
40.1 to 60 lbs	810	13.5	One
60.1 to 120 lbs	1620	27	One
Over 120 lbs	Administer the appropriate combination of tablets		

Administer TRIFEXIS with food for maximum effectiveness. To ensure heartworm prevention, owners should observe the dog for one hour after dosing. If vomiting occurs within an hour of administration, redose with another full dose. If a dose is missed and a monthly interval between doses is exceeded, then immediate administration of TRIFEXIS with food and resumption of monthly dosing will minimize the opportunity for the development of adult heartworm infections and flea reinfestations.

#### Heartworm Prevention:

TRIFEXIS should be administered at monthly intervals beginning within 1 month of the dog's first seasonal exposure and continuing until at least 3 months after the dog's last seasonal exposure to mosquitoes (see **EFFECTIVENESS**), TRIFEXIS may be administered year round without interruption. When replacing another heartworm preventative product, the first dose of TRIFEXIS should be given within a month of the last dose of the former medication.

#### Flea Treatment and Prevention:

Treatment with TRIFEXIS 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 TRIFEXIS should continue the entire year without interruption.

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

#### Intestinal Nematode Treatment and Control:

TRIFEXIS also provides treatment and control of roundworms (*T. canis, T. leonina*), hookworms (*A. caninum*) and whipworms (*T. vulpis*). Dogs may be exposed to and can become infected with roundworms, whipworms and hookworms throughout the year, regardless of season or climate. Clients should be advised of measures to be taken to prevent reinfection with intestinal parasites.

#### **Contraindications:**

There are no known contraindications to the use of TRIFEXIS.

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, a component of TRIFEXIS (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 *D. immitis*. While the number of circulating microfilariae may decrease following treatment, TRIFEXIS is not indicated for microfilariae clearance (see ANIMAL SAFETY).

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

Use with caution in breeding females (see ANIMAL SAFETY). The safe use of TRIFEXIS in breeding males has not been evaluated.

Use with caution in dogs with pre-existing epilepsy (see ADVERSE REACTIONS). Puppies less than 14 weeks of age may experience a higher rate of vomiting (see ANIMAL SAFETY).

#### Adverse Reactions

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

Over the 180-day study period, all observations of potential adverse reactions were recorded. Reactions that occurred at an incidence >1% (average monthly rate) within any of the 6 months of observation are presented in the following table. The most frequently reported adverse reaction in dogs in the TRIFEXIS group was vomiting.

Average Monthly Rate (%) of Dogs With Adverse Reactions

Adverse Reaction	TRIFEXIS Chewable Tablets <sup>a</sup>	Active Control Tablets <sup>a</sup>
Vomiting	6.13	3.08
Pruritus	4.00	4.91
Lethargy	2.63	1.54
Diarrhea	2.25	1.54
Dermatitis	1.47	1.45
Skin Reddening	1.37	1.26
Decreased appetite	1.27	1.35
Pinnal Reddening	1.18	0.87

an=176 dogs

In the US field study, one dog administered TRIFEXIS experienced a single mild seizure 2 ½ 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 suspected adverse drug events, contact Elanco Animal Health at 1-888-545-5973. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/Animal/Veterinary/SafetyHealth

#### Post Approval Experience (Mar 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.

#### Mode of Action:

The primary target of action of spinosad, a component of TRIFEXIS, is an The primary target of action of spinosad, a component of HHEADs, is an activation of incionic acetylcholine receptors (nAChRs) in insects. Spinosad does not interact with known insecticidal binding sites of other nicotinic or GABAergic insecticides such as neonicotinoids, fiproles, milbemycins, avermectins and cyclodienes. Insects treated with spinosad show involuntary muscle contractions and tremors resulting from activation of motor neurons. Prolonged and demons resuming norm activation of mixed metrons. Protections, paralysis and flea death. The selective toxicity of spinosad between insects and vertebrates may be conferred by the differential sensitivity of the insect versus vertebrate nAChRs.

Milbemycin oxime, a component of TRIFEXIS, acts by binding to glutamate-gated chloride ion channels in invertebrate nerve and muscle cells, Increased permeability by the cell membrane to chloride ions causes hyperpolarization of affected cells and subsequent paralysis and death of the intended parasites. Milbemycin oxime may also act by disrupting the transmission of invertebrate neurotransmitters, notably gamma amino butyric acid (GABA).

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. Spinosad, a component of TRIFEXIS, kills 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 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.

TRIFEXIS is a flavored chewable tablet. In a field study of client-owned dogs where 175 dogs were each offered TRIFEXIS once a month for 6 months, dogs voluntarily consumed 54% of the doses when offered plain as if a treat, and 33% of the doses when offered in or on food. The remaining 13% of doses were administered like other tablet medications

Animal Safety: TRIFEXIS was tested in pure and mixed breeds of healthy dogs in well-controlled clinical and laboratory studies. No dogs were withdrawn from the field studies due to treatment-related adverse reactions.

In a margin of safety study, TRIFEXIS was administered orally to 8-week-old Beagle puppies at doses of 1, 3, and 5 times the upper half of the therapeutic dose band, every 28 days for 6 dosing periods. Vomiting was seen in all groups including control animals with similar frequency. Adverse reactions seen during the course of the study were salivation, tremors, decreased activity, coughing and vocalization.

Body weights were similar between control and treated groups throughout the study. Treatment with TRIFEXIS was not associated with any clinically significant hematology, clinical chemistry or gross necropsy changes. One 5X dog had minimal glomerular lipidosis observed microscopically. The clinical relevance of

Plasma spinosyn A, spinosyn D, milbemycin A<sub>3</sub> 5-oxime and milbemycin A<sub>4</sub> 5-oxime concentrations increased throughout the study. At each dosing period, 5-oxime concentrations increased unroughout the study. At each costing behavior plasma spinosyn A and spinosyn D concentrations were greater than proportional across the dose range 1 to 5X. Plasma milbemycin A<sub>4</sub> 5-oxime concentrations appeared to be dose proportional across range 1 to 5X by the end of the study. Plasma concentrations of spinosad and milbemycin oxime indicate that expected systemic exposures were achieved throughout the study.

In an avermectin-sensitive Collie dog study, TRIFEXIS was administered orally at 1, 3, and 5 times the upper half of the recommended therapeutic dose band every 28 days. No signs of avermectin sensitivity were observed after administration of TRIFEXIS during the study period to avermectin-sensitive Collie dogs. The adverse reactions observed in the treatment groups were vomiting and diarrhea. Body weights in all treatment groups were comparable to the control group. Hematology and clinical chemistry parameters showed no clinically significant changes from study start to end, and all dogs were considered healthy throughout the study.

In a heartworm positive safety study, TRIFEXIS was administered orally at 1, 3, and 5 times the upper half of the therapeutic dose band to Beagle dogs with and 5 times the upper half of the therapeutic dose band to beggle dogs with adult heartworm infections and circulating microfilariae, every 28 days for 3 treatments. Vomiting was observed in one dog in the 1X group, in three dogs in the 3X group, and in one dog in the 5X group. All but one incident of vomiting was observed on the treatment day during the first treatment cycle. The vomiting was mild and self-limiting. Hypersensitivity reactions were not observed in any of the treatment groups. Microfilariae counts decreased with treatment.

the treatment groups, wincomainate occunis decreases with treatments and in a reproductive safety study, TRIFEXIS was administered orally to female dogs at 1 and 3 times the upper half of the therapeutic dose band every 28 days prior to matting, during gestation and during a six-week lactation period. Dogs with confirmed fetal heartbeats on ultrasound examination were evaluated for reproductive safety. One 3X and one 1X group female did not become pregnant. No treatment-related adverse reactions or signs of avermectin toxicosis were noted for adult females, Adult females in the 3X group lost weight during the 6-week pre-matting period, while control group females gained weight during that time. The body weights of the tracted groups were comparable to their that time. The body weights of the treated groups were comparable to the control group during gestation and post-parturition phases of the study. Gestation length, litter average body weight, litter size, stillborn pups, pup survival and the proportion of pups with malformations were comparable between treated and control dam groups. Malformations in the 1X group included a pup with deft palate and a litermate with anophthalmia, fused single nares, misshapen palate, hydrocephalus, omphalocele and malpositioned testes; a pup with a malformation of the anterior tip of the urinary bladder and umbilical blood vessel; and a pup with patent ductus arteriosus (PDA). Malformations in the 3X group included three littermates with PDA. Malformations in the control the 3X group included three littermates with PDA. Malformations in the control group included a pup with a malformed sternum and a pup with PDA and a malpositioned superior vena cava. Clinical findings in pups of the treated groups were comparable to the control group except for one 1X group pup that was smaller and less coordinated than its littermates and had tremors when excited. The relationship between spinosad and milbemycin oxime treatment and the 1X and 3X dogs that did not become pregnant, the specific pup malformations and the unthrifty 1X group pup are unknown. The incidence of cleft palate is not unexpected based on the historical data collected at the breeding site.

In a margin of safety study with spinosad alone, 6-week old Beagle pupples were administered average doses of 1.5, 4.4, and 7.4 times the maximum recommended dose at 28-day intervals over a 6-month period. Vomitting was observed across all treatments, including controls, and was observed at an increased rate at elevated doses. Vomiting most often occurred 1 hour following administration and decreased over time and stabilized when puppies reached 14 weeks of age.

#### Storage Information:

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

How Supplied: TRIFEXIS is available in five tablet sizes. Each tablet size is available in color-coded packages of 6 tablets. 5-10 lbs (140 mg spinosad and 2.3 mg milbemycin oxime)

10.1-20 lbs (270 mg spinosad and 4.5 mg milbemycin oxime) 20.1-40 lbs (560 mg spinosad and 9.3 mg milbemycin oxime) 40.1-60 lbs (810 mg spinosad and 13.5 mg milbernycin oxime) 60.1-120 lbs (1620 mg spinosad and 27 mg milbernycin oxime)

NADA 141-321, Approved by the FDA

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