# Brave virtual world: Find success with product sales

Build systems that give your team confidence when they make product recommendations—and leverage your competitive edge.

By Brian Conrad, CVPM

Pet owners have so many places today where they can buy products and fill prescriptions. Online. Pet stores. Box stores. There's more competition than ever. So how can veterinary practices compete?

Box stores get the edge because they offer so many options, but veterinary hospitals offer education and recommendations. That's our edge. If you want what your veterinarian thinks is the very best for your pet, you buy what your veterinarian recommends.

You know better than anyone the power of the bond between people and their pets. We do what we do to protect that relationship and make it a long and happy one. It's our job to advocate for the pet—and for the care that protects the relationship. And, that's true whether we're talking about services or products.

Here's a benchmark for you: People today take more pictures of their pet than of their spouse or family. When they bring that beloved pet to the veterinary hospital, they're experiencing two main emotions: Hope and fear. They hope the visit goes well. They hope there's good news. They hope nothing negative will be found. They're scared the dog might pee on the bags of dog food in the reception area. They're scared the dog will bite someone and embarrass them. They're scared the doctor might find a lump. (And, if she did, with every passing minute, we're more convinced that it's cancer.)

# It's our job to instill hope and alleviate the fear.

That's really at the core of what we do. If you look at my practice's mission statement, the key elements are about partnering with each client to encourage and educate them as they care for their pet. As part of living that mission, we recommend products. Offering pet owners the products they need for their pets is foundational to our mission. To accomplish that, we build a broad foundation that supports our product recommendations. We're never just running a "buy one, get one free" promotion. We're always living our role as advocates.

In my practice, we committed to this path when we realized that all kinds of other sources were making recommendations—and they're far less qualified to give pet owners the information they really need. Within a mile of my practice, you'll find a dozen other choices if you're looking for pet products. I was at puppy training with my own pup, Leo, and all the pet owners leaned in to hear what the trainer said about what to feed our puppies. I was really taken aback. What?! She's not an expert. If we don't give a strong recommendation, someone else will.

Of course, that's just one example of less qualified sources making pet health recommendations. There are many more. And so, in my own practices, we chose to re-focus our efforts. We refocused on product sales because we're committed to the best care and to the health and well-being of pets.

Our structured approach to product sales lead to better client compliance. We increased profits for the practice. We used that additional money we earned to pay our team more, upgrade our equipment, and maintain our facility. All of that makes for a happy team. And a happy team takes great care of pets and pet owners. It's a reinforcing cycle.

We're obviously still centered around services, but we no longer overlook the benefits of offering products to our clients—benefits for them, for their pets, and for our practice. Clients want what's best for their pets and we're here to say what that is.

# 5 steps to success

It's key to me that these solutions rely on our team—not on our location, facility, or the size of the business. These are people-to-people solutions. With that said, our system for long-term success around product recommendations rests on the following foundation:

# 1. Consistent message from doctors

At one point, I felt like we offered five options for every product. Five choices of food for every dog. Five dental care treats. Every lunch and learn added a product. When we got focused on product sales, we knew we needed to make clear and consistent recommendations. Part of our path was to decide on one line of products. One protocol. We do have one back-up option for cases when our core product or protocol just isn't appropriate. But for most cases, we offer the same thing, every time.

If it's a wellness visit, and we're talking about a dewormer, we offer the same thing every time. We have a staff of 60, and we all know what the recommendation is. We literally made stickers to put on the products we recommend, to make absolutely sure the client knows that we made the recommendation.

# 2. Staff training

Knowing what products we recommend and being prepared to answer clients' questions about them is part of every team member's job description. And, I mean that literally. Learning to make a confident recommendation is built into our training protocol. We discuss this element of advocacy for patients in our annual evaluations. We build product recommendations into our practice's systemic approach to advocacy.

Let's take Imoxi™ (Imidacloprid + Moxidectin) as an example. When we decide that we're going to carry a product, we'll start with 30 minutes of practical information during a staff training meeting. We don't dig deep into the science of how the parasiticide works. Instead, we focus

on questions clients are likely to ask. Given that, we'd talk about the fact that Imoxi offers proven protection against fleas, heartworms and intestinal parasites; uses a trusted combination of ingredients; is available at a lower price; kills fleas through contact; provides long-lasting intestinal parasite coverage; and is easy to apply. The goal is to prepare our team to answer clients' questions and build clients' confidence. (For full prescribing information, see end of document.)

A couple of nitty-gritty notes here: I recommend that you have the product in the practice and ready to sell before you do a training meeting or a lunch and learn. Everyone is excited to get started when you finish the training, and in my experience, we need to be ready to go right then—not in four weeks when we get the product in and add it to our systems.

I also recommend that you think carefully about how you use staff incentives. You want any incentive to be good for the practice—not cause animosity or competition. So, it needs to be fair! While I do love samples, we don't give our team members samples of any products we don't actually carry or recommend. We want to walk the talk on our recommendations, so it's key for our team members to use the products we offer our clients for their own pets.

After the group training, we do small break outs with groups of two to four team members to drill down and discuss the answers to common client questions. These smaller groups keep everyone focused and engaged, and this approach gives everyone a chance to practice talking about the product in a less stressful environment.

I also use a follow-up quiz to make sure everyone is on the same page. For example, I might ask everyone to name three benefits of using Imoxi. All these methodical efforts ensure that every team member can talk to clients about the products we believe in with consistency and confidence.

### 3. Educate the client

Let's say a brother and sister each put up a lemonade stand in the front yard. The brother charges \$2 a glass, and the sister charges 50 cents. Who do you think you'll buy your lemonade from? Now, let's say that the brother puts up an educational sign that reads, "Made with clean water." When you ask, you learn the sister made her lemonade using water from the pond. Now who would you buy from? That's the power of education.

The doctor is often in a position to start the education when she or he finds something that needs to be discussed during the exam. It might be the pet's weight, or dental disease or parasite control. We work at finding creative ways to help pet owners understand the health issues we raise by making the education clear, specific and concrete.

For example, we were finding that one in five pets who visited the practice tested positive for parasites. So, we made a poster showing pictures of five healthy looking pets and we put it up in each exam room. Now we say, "Which of these pets do you think has a parasite? We don't

know either, unless we do the tests, but one in five does." That approach makes the message specific to our practice and the risk to that pet very concrete.

The next step is to make a recommendation. It's still common in practices for doctors to take the path of least resistance and avoid a direct recommendation. They don't want to feel sales-y.

My practice team used to sidestep, too. Back in 2001, we would ask pet owners if they wanted pre-anesthetic blood work. Or, we'd give them choices about what kind of pain medication we'd use. We were asking them to play doctor and make important medical decisions about things they really didn't know anything about. Why do we worry so much about clients' responses to our recommendations? We worry so much, sometimes, that we don't make the recommendation at all.

Now, our practice team does make the strong recommendation. And, our whole team knows we do it because we care about the well-being of pets. Everyone helps reinforce the message. Each team member knows his or her role in getting that pet the best possible care and in building the relationship with the pet owner.

# 4 Make it easy

The first step is to have the product you're recommending available to your clients. Of course, I'm not advocating that you carry every single product. That's part of why I think it's important to agree to a more limited set of recommendations. But once that's done, you need to keep those products in stock. Clients don't want to come back in a week, because you happened to run out!

To be prepared, you need to look ahead. For example, with a product such as Imoxi, you should have 30- to 60-day turns on the shelf. A week's worth of product just won't work out, because sales fluctuate. At our practice, if we're ever out of stock of something, we deliver it to the client's house for free. I figure, if we can't manage our inventory, that's on us.

The next step is to make it easy for the client. What do you do for the client who's coming by over their lunch break? Remember, they're making a special trip to see you rather than buying something when they're at the box store anyway or shopping online. We let the client text us. We get their order all ready, so they're in and out.

Finally, it's important to make sure our pricing is competitive, too. One way to do that is to offer generic options. Clients are used to buying all kinds of generics for their own healthcare. They'll appreciate you looking for ways to save them money on a product that you believe in. That's a real opportunity to please your client.

# 5. Follow up and follow through

Let's say everything goes according to plan. The client understands the need and buys the product we recommend. That's great! But, it's not the end of the path. The last thing we want is for them to think that now we made the sale, we don't care. Let's make sure we get all the way to the goal, which is a long-term relationship with the pet owner, and the best possible care for the pet.

At my practice, if a client isn't happy with a product, we take it back. If they're worried they won't administer it right, we'll do it for them. We're in this for the long term, not for this one purchase. If the client has concerns, we need to fix them. We want to support the client and consistently build their trust in us. When they come back to the practice, we want to celebrate that their pet got 12 months of parasite control and lost those extra three pounds. We want to congratulate them on the care they provide.

Every client we see loves their pet, or they wouldn't be spending their time, money and energy to visit a veterinary practice. Wanting that pet to stay healthy and happy is what we have in common. Let's be strong partners, and find ways to offer all the care that pet needs—including the products we believe in.

CAUTION: Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian. Dogs: WARNING: **DO NOT ADMINISTER THIS PRODUCT ORALLY**. For the first 30 minutes after application, ensure that dogs cannot lick the product from application sites on themselves or other treated animals. Children should not come in contact with the application sites for two (2) hours after application. (See Contraindications, Warnings, Human Warnings and Adverse Reactions for more information.) Cats: Do not use on sick, debilitated, or underweight cats. Avoid oral ingestion. For full prescribing information, visit <a href="https://www.vetoquinolusa.com/imoxi-info">www.vetoquinolusa.com/imoxi-info</a>

IMX-0449-BCPRC

# **IMOXI™** Topical Solution for Dogs (imidacloprid + moxidectin)

Once-a-month topical solution for the prevention of heartworm disease, the treatment of circulating microfilariae, kills adult fleas, is indicated for the treatment of flea infestations, the treatment and control of sarcoptic mange, as well as the treatment and control of intestinal parasite infections in dogs and puppies that are at least 7 weeks of age and that weigh at least 3 lbs.

- DO NOT ADMINISTER THIS PRODUCT ORALLY
- For the first 30 minutes after application ensure that dogs cannot lick the product from application sites on themselves or other treated animals.

   Children should not come in contact with application sites for two (2) hours after application.

(See Contraindications, Warnings, Human Warnings, and Adverse Reactions

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

IMOXI™ Topical Solution for Dogs (10% imidacloprid + 2.5% moxidectin) is a colorless to yellow ready-to-use solution packaged in single dose applicator tubes for topical treatment of dogs. The formulation and dosage schedule are designed to provide a minimum of 4.5 mg/lb. (10 mg/kg) imidacloprid and 1.1 mg/lb. (2.5 mg/kg) moxidectin based on body weight.

Imidaclopid is a chloronicotiny introguandine insecticide. The chemical name for imidaclopid is 1-([6-Choro - 3-pyridinyl) methyl]-N-ritro-2-imidazolidininine. Moxidectin is a semisynthetic macrocyclic lactone endectocide derived from the actinomycete Streptomycetes cyaneogriseus noncyanogenus. The chemical name for moxidectin is [6R, 235, 255([5])-5-O-Demethyl-28-deoxy-25-(1,3-dimeth)-1- butenyl)-6.28-epoxy-23-(methoxyimino) milbemycin B.

INDIATIONS:

INDXI™ Topical Solution for Dogs is indicated for the prevention of heartworm disease caused by 
Dirofilaria immitis and the treatment of Dirofilaria immitis circulating microfilariae in heartworm-positive dogs. IMOXI™ Topical Solution for Dogs kills adult fleas and is indicated for the treatment of flea 
infestations (Clenocephalides felis). IMOXI™ Topical Solution for Dogs is indicated for the treatment 
and control of sarcoptic mange caused by Sarcoptes scablei var. canis. IMOXI™ Topical Solution for 
Dogs is also indicated for the treatment and control of the following intestinal parasites:

Intestinal Parasite		Intestinal Stage		
		Adult	Immature Adult	Fourth Stage Larvae
Hookworm	Ancylostoma caninum	Х	Х	Х
Species	Uncinaria stenocephala	Х	Х	Х
Roundworm Species	Toxocara canis	Х		Х
	Toxascaris leonina	Х		
Whipworm	Trichuris vulpis	Χ		

#### CONTRAINDICATIONS:

Do not administer this product orally. (See WARNINGS)

Do not use this product (containing 2.5% moxidectin) on cats.

#### WARNINGS:

For the first 30 minutes after application:

Ensure that dogs cannot lick the product from application sites on themselves or other treated dogs, and separate treated dogs from one another and from other pets to reduce the risk of accidental ingestion.

Ingestion of this product by dogs may cause serious adverse reactions including depression, salivation, dilated pupils, incoordination, panting, and generalized muscle tremors.

In avermectin sensitive dogs, at the signs may be more severe and may include coma and

"Some dogs are more sensitive to avermectins due to a mutation in the MDR1 gene. Dogs with this mutation may develop signs of severe avermectin toxicity if they ingest this product. The most common breeds associated with this mutation include Collies and Collie crosses.

<sup>a</sup> Although there is no specific antagonist for avermectin toxicity, even severely affected dogs have completely recovered from avermectin toxicity with intensive veterinary supportive care.

### HUMAN WARNINGS:

Not for human use. Keep out of the reach of children.

Children should not come in contact with application sites for two (2) hours after application. Causes eye irritation. Harmful if swallowed. Do not get in eyes or on clothing. Avoid contact with skin. Exposure to the product has been reported to cause headache; dizziness; and redness, burning. tingling, or numbness of the skin.

### Wash hands thoroughly with soap and warm water after handling.

If contact with eyes occurs, hold eyelids open and flush with copious amounts of water for 15 minutes. If eye irritation develops or persists, contact a physician. If swallowed, call poison control center or physician immediately for treatment advice. Have person sip a glass of water if able to swallow. Do in finduce vomitting unless told to do so by the poison control center or physician. People with known hypersensitivity to benzyl alcohol, imidacloprid or moxidectin should administer the product with caution. In case of allergic reaction, contact a physician. If contact with skin or clothing occurs, take off contaminated clothing. Wash skin immediately with plenty of soap and water. Call a poison control center or physician for treatment advice.

The Safety Data Sheet (SDS) provides additional occupational safety information. For consumer

questions call 1-000-03-049b.

For a copy of the Safety Data Sheet (SDS) or to report adverse reactions call Vetoquinol USA, Inc. at 1-800-835-9496.

Do not dispense dose applicator tubes without complete safety and administration information Use with caution in sick, debilitated, or underweight animals. The safety of IMOXI™ Topical Solution for Dogs has not been established in breeding, pregnant, or lactating dogs. The safe use of IMOXI™ Topical Solution for Dogs has not been established in puppies and dogs less than 7 weeks of age or less than 3 lbs. body weight.

less than 3 lbs. body weight.

Prior to administration of IMOXI™ Topical Solution for Dogs, 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. The safety of IMOXI™ Topical Solution for Dogs has not been evaluated when administered on the same day as an adulticide. IMOXI™ Topical Solution for Dogs is not effective against adult D. immilis. Although the number of circulating microfliariae is substantially reduced in most dogs following treatment with IMOXI™ Topical Solution for Dogs, the microfiliaria count in some heartworm-positive dogs may increase or remain unchanged following treatment with IMOXI™ Topical Solution for Dogs, alone or in a dosing regimen with melarsomine divibror/policity.

(See ADVERSE REACTIONS and ANIMAL SAFETY - Safety Study in Heartworm-Positive Dogs. IMOXI™ Topical Solution for Dogs has not been evaluated in heartworm-positive dogs with Class 4 heartworm disease

### ADVERSE REACTIONS:

# Heartworm-Negative Dogs

Field Studies: Following treatment with imidacloprid and moxidectin topical solution or an active control, dog owners reported the following post-treatment reactions:

imidacloprid and moxidectin topical solution n=128	Active Control n=68
19 dogs (14.8%)	7 dogs (10.3%)
9 dogs (7.0%)	5 dogs (7.4%)
5 dogs (3.9%)	None observed
1 dog (0.8%)	1 dog (1.5%)
1 dog (0.8%)	1 dog (1.5%)
1 dog (0.8%)	None observed
	topical solution n=128 19 dogs (14.8%) 9 dogs (7.0%) 5 dogs (3.9%) 1 dog (0.8%) 1 dog (0.8%)

During a field study using 61 dogs with pre-existing flea allergy dermatitis, one (1.6 %) dog experienced localized prurifus immediately after imidacloprid application, and one investigator noted hyperkeratosis at the application site of one dog (1.6 %).

In a field safey and effectiveness study, imidacloprid and moxidectin topical solution was administered to 92 client-owned dogs with sarcoptic mange. The dogs ranged in age from 2 months to 12.5 years and ranged in weight from 3 to 231.5 pounds. Adverse reactions in dogs treated with imidacloprid and moxidectin topical solution included hematochezia, diarrhea, vomiting, lethargy,

Laboratory Effectiveness Studies: One dog in a laboratory effectiveness study experienced weakness, depression, and unsteadiness between 6 and 9 days after application with imidacloprid and moxidectin topical solution. The signs resolved without intervention by day 10 post-application. The signs in this dog may have been related to peak serum levels of moxidectin, which vary between dogs, and occur between 1 and 21 days after application of imidacloprid and moxidectin topical solution.

The following clinical observations also occurred in laboratory effectiveness studies following application with imidacloprid and moxidectin topical solution and may be directly attributed to the drug or may be secondary to the intestinal parasite burden or other underlying conditions in the dogs: diarrhea, bloody stools, vomitting, anorexia, lethargy, coughing, coular discharge and nasal discharge. Observations at the application sites included damp, stiff or greasy hair, the appearance of a white deposit on the hair, and mild erythema, which resolved without treatment within 2 to 48

#### Heartworm-Positive Dogs

Field Study: A 56-day field safety study was conducted in 214 D. Immitis heartworm and microfilaria positive dogs with Class 1, 2 or 3 heartworm disease. All dogs received imidadoprid and moxidectin topical solution on Study Days 6 and 28; 108 dogs also received melarsomine dihydrocthoride on Study Days – 14, 14, and 15. All dogs were hospitalized for a minimum of 12 hours following each treatment. Effectiveness against circulating D. Immitis microfilariae was > 90 % at five of six sites; however, one site had an effectiveness of 73.3 %. The microfilaria ount in some heartworm-positive dogs increased or remained unchanged following treatment with imidacloprid and moxidectin topical solution alone or in a dostine receims with melarsomine difficult horized. solution alone or in a dosing regimen with melarsomine dihydrochloride.

Following treatment with imidacloprid and moxidectin topical solution alone or in a dosing regimen

with melarsomine dihydrochloride, the following adverse reactions were observed.

Adverse Reaction	Dogs Treated with imidacloprid and moxidectin topical solution n=106	Dogs Treated with imidacloprid and moxidectin topical solution + Melarsomine n=108
Cough	24 (22.6%)	25 (23.1%)
Lethargy	14 (13.2%)	42 (38.9%)
Vomiting	11 (10.4%)	18 (16.7%)
Diarrhea, including hemorrhagic	10 (9.4%)	22 (20.4%)
Inappetence	7 (6.6%)	19 (17.6%)
Dyspnea	6 (5.7%)	10 (9.3%)
Tachypnea	1 (<1%)	7 (6.5%)
Pulmonary Hemorrhage	0	1 (<1%)
Death	0	3 (2.8%)

Three dogs treated with imidacloprid and moxidectin topical solution in a dosing regimen with melarsomine dihydrochloride died of pulmonary embolism from dead and dying heartworms. One dog, treated with imidacloprid and moxidectin topical solution and melarsomine dihydrochloride, experienced pulmonary hemorrhage and responded to supportive medical treatment. Following the first treatment with imidacloprid and moxidectin topical solution alone, two dogs experienced adverse reactions (coupling, wornting, and dyspeneal that required hospitalization. In both groups, there were more adverse reactions to imidacloprid and moxidectin topical solution following the first treatment than the second treatment.

To report a suspected adverse reaction, call 1-800-835-9496.

#### Post-Approval Experience:

The following adverse events are based on post-approval adverse drug experience reporting. Not all

The following adverse events are based on post-approval adverse drug experience reporting. Not all adverse reactions are reported to FDA CVM. It is not always possible to reliably estimate the adverse event frequency or establish a causal reliationship to product exposure using this data. The following adverse events in dogs are fisted in decreasing order of reporting frequency depression(lethargy, vomiting, puritus, diarrhea, annorsia, hyperactivity, ataxia, trembling, hypersalivation, application site reactions (alopecia, pruritus, lesions, and erythema), seizures, and anaphylaxis/anaphylactic reactions (hives, urticaria, facial swelling,

## Serious reactions, including neurologic signs and death have been reported when cats have

been exposed (orally and topically) to this product.

In humans, nausea, numbness or tingling of the mouth/ lips and throat, ocular and dermal irritation, pruritus, headache, vomiting, diarrhea, depression and dyspnea have been reported following exposure to this product.

To report suspected adverse drug events, for technical assistance or to obtain a copy of the SDS, contact Vetoquinol USA, Inc. at 1-800-835-9496.

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/ reportanimalae

### DOSAGE AND ADMINISTRATION:

The recommended minimum dose is 4.5 mg/lb. (10 mg/kg) imidacloprid and 1.1 mg/lb. (2.5 mg/kg) moxidectin, once a month, by topical administration.

### Do not apply to irritated skin.

Remove one dose applicator tube from the package. As specified in the table, administer the entire contents of the IMOXI<sup>™</sup> Topical Solution for Dogs tube that correctly corresponds with the body weight of the dog.

weight of the dog.			
Dog (lbs.)	Volume (mL)	Imidacloprid (mg)	Moxidectin (mg)
3–9	0.4	40	10
9.1–20	1.0	100	25
20.1-55	2.5	250	62.5
55.1-88	4.0	400	100
88 1 110 *	5.0	500	125

Dogs over 110 lbs. should be treated with the appropriate combination of IMOXI™ Topical Solution

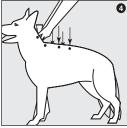




2. While holding the Twist•N•Go™ tube in an upright position, twist the dispensing cap clockwise

about 1/2 turn to break the tube's seal. Remove the cap from the tube





3. The dog should be standing for application. Position the dispensing tip on the dog's back between the shoulder blades. The dispensing tip of the tube can be used to part the dog's hair until the skin is

VISIDIA.

4. For dogs weighing 20 lbs. or less, place the tip of the tube on the skin and apply the entire contents directly on the exposed skin at one spot between the shoulder blades. For dogs weighing more than 20 lbs., place the tip of the tube on the skin and apply the entire contents directly on the exposed skin at 3 or 4 spots on the top of the backline from the base of the neck to the tupper back in an area inaccessible to licking. Do not apply an amount of solution at any one location that could run off the side of the dog.

Do not let this product get in your dog's mouth or eyes. **Do not allow the dog to lick any of the application sites for 30 minutes.** In households with multiple pets, keep each treated dog separated from other treated dogs and other pets for 30 minutes after application to prevent licking

#### (See WARNINGS)

Stiff hair, a damp appearance of the hair, pink skin, or a slight powdery residue may be observed at the application site on some animals. This is temporary and does not affect the safety and effectiveness of the product.

Shampooing 90 minutes after treatment does not reduce the effectiveness of IMOXI™ Topical Solution for Dogs in the prevention of heartworm disease. Shampooing or water immersion 4 days after treatment will not reduce the effectiveness of IMOXI™ Topical Solution for Dogs in the treatment of flea infestations. However, shampooing as often as once weekly may reduce the effectiveness of the product against fleas.

Heartworm Prevention: For prevention of heartworm disease, IMOXI™ Topical Solution for Dogs should be administered at one-month intervals. IMOXI™ Topical Solution for Dogs may be administered year-round or at a minimum should start one month before the first expected exposure to mosquitoes and should continue at monthly intervals until one month after the last exposure to mosquitoes. If a dose is missed and a 30-day interval between doses is exceeded, administer IMOXI memory and the start of ™ Topical Solution for Dogs immediately and resume the monthly dosing schedule. When replacing another heartworm preventative product in a heartworm prevention program, the first treatment with IMOXI™ Topical Solution for Dogs should be given within one month of the last dose of the former

Treatment of Circulating Microfilaria: For the treatment of circulating D. immilis microfilaria in heartworm-positive dogs, IMOXI™ Topical Solution for Dogs should be administered at one-month intervals. Treatment with an approved adulticide therapy is recommended because IMOXI™ Topical Solution for Dogs is not effective for the treatment of adult D. immilis.

#### (See PRECAUTIONS)

I NEED NOTION 3

Thea Treatment: For the treatment of flea infestations, IMOXI™ Topical Solution for Dogs should be administered at one-month intervals. If the dog is already infested with fleas when the first dose of IMOXI™ Topical Solution for Dogs is administered, adult fleas on the dog will be killed. However, reinfestation from the emergence of preexisting pupae in the environment may continue to occur for six weeks or longer after treatment is initiated. Dogs treated with imidactoprid, including those with pre-existing flea altergy dermatitis have shown clinical improvement as a direct result of elimination of fleas from the dog. of fleas from the dog.

Treatment and Control of Intestinal Nematode Infections: For the treatment and control of

intestinal hookworm infections caused by Ancylostoma caninum and Uncinaria stenocephala (adults immature adults and fourth stage larvae) and roundworm infections caused by *Toxocara canis* (adults and fourth stage larvae), and *Toxascaris leonina* (adults), and whipworm infections caused by *Trichurs vulpis* (adults), IMOXI™ Topical Solution for Dogs should be administered once as a single tonical dose

Treatment and Control of Sarcoptic Mange: For the treatment and control of sarcoptic mange caused by Sarcoptes scabiei var. canis, IMOX1<sup>™</sup> Topical Solution for Dogs should be administered as a single topical dose. A second monthly dose may be administered if necessary. ANIMAL SAFETY:

## Heartworm-Negative Dogs

Field Study: In a controlled, double-masked, field safety study, imidacloprid and moxidectin topical solution was administered to 128 dogs of various breeds, 3 months to 15 years of age, weighing 4 to 157 pounds. Imidacloprid and moxidectin topical solution was used safely in dogs concomitantly 137 pourius, limitacioni atun inxiderium optical solution was used salely in dogs concentialiny receiving ACE inhibitors, anticonvulsants, antihistamines, antimicrobials, cohardroprotectants, corticosteroids, immunotherapeutics, MAO inhibitors, NSAIDs, ophthalmic medications, sympathominetics, synthetic estrogens, thyroid hormones, and urinary acidifiers. Owners reported the following signs in their dogs after application of imidacloprid and moxidectin topical solution: pruritus, flaky/greasy residue at the treatment site, medicinal odor, lethargy, inappetence, and hyperactivity.

### (See ADVERSE REACTIONS)

Safety Study in Puppies: Imidacloprid and moxidectin topical solution was applied topically at 1, 3 Sately Study in Explices. Initial colonia in a link installation (pickal solution was applied topically at 1, 3 and 5X the recommended dose to 7-week-old Beagle puppies once every 2-weeks for 6 treatments on days 0, 14, 28, 42, 56, and 70. Loose stools and diametriae were observed in all groups, including the controls, throughout the study. Vorniting was seen in one puppy from the 1X treatment group (day 1, 1 wo puppies aced in the 1X, 3X, and 5X groups had decreased appetities within 24 hours post-dosing. One puppy in the 1X treatment group had pruritus for one hour following the fifth treatment. A puppy from the 5X treatment group displayed rapid, difficult breathing from 4 to 8 hours following the second testiment. 8 hours following the second treatment.

Dermal Dose Tolerance Study: Imidacloprid and moxidectin topical solution was administered topically to 8-month-old Beagle dogs at 10X the recommended dose once. One dog showed signs of treatment site irritation after application. Two dogs vomitted, one at 6 hours and one at 6 days post-treatment. Increased RBC, hemoglobin, advised partial thromboplastin, and direct bitriush were observed in the treated group. Dogs in the treated group did not gain as much weight as the

Control group.

Oral Safety Study in Beagles: Imidadoprid and moxidectin topical solution was administered once orally at the recommended topical dose to 12 dogs. Six dogs vomited within 1 hour of receiving the test article, 2 of these dogs vomited again at 2 hours, and 1 dog vomited again up to 18 hours post-dosing. One dog exhibited shaking (nervousness) 1 hour post-dosing. Another dog exhibited abnormal neurological signs (circling, ataxia, generalized muscle tremors, and dilated pupils with a slow pupillary light response) starting at 4 hours post-dosing through 18 hours post-dosing. Without treatment, this dog was neurologically normal at 24 hours and had a normal appetite by 48 hours

### (See CONTRAINDICATIONS)

Dermal Safety Study in Ivermectin-Sensitive Collies: Imidacloprid and moxidectin topical solution was administered topically at 3 and 5X the recommended dose every 28 days for 3 treatments to Collies which had been prescreened for avermectin sensitivity. No clinical abnormalities were

Observed.

Oral Safety Study in Ivermectin-Sensitive Collies: Imidacloprid and moxidectin topical solution was administered orally to 5 pre-screened ivermectin-sensitive Collies. The Collies were asymptomatic after ingesting 10% of the minimum labeled dose. At 40% of the minimum recommended topical dose, 4 of the dogs experienced neurological sign indicative of avermectin toxicity including depression, ataxia, mydriasis, salivation, muscle fasciculation, and coma, and were euthanized.

## (See CONTRAINDICATIONS)

### Heartworm-Positive Dogs

Heartworm-Positive Dogs
Laboratory Safey Study in Heartworm-Positive Dogs: Imidacloprid and moxidectin topical solution was administered topically at 1 and 5X the recommended dose every 14 days for 3 treatments to dogs with adult heartworm infections and circulating microfliaria. At 5X, one dog was observed vomiting three hours after the second treatment. Hyperensitivity reactions were not seen in the 5X treatment group. Microfilaria counts decreased with treatment.

### STORAGE INFORMATION:

Store at temperatures between 20° C (68 °F) and 25° C (77 °F), avoiding excess heat or cold.

Applications Per Package 6 x 0.4 mL tubes 6 x 1.0 mL tubes



Vetoquinol USA, Inc.

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6 x 4.0 mL tubes

6 x 5.0 mL tubes

# **IMOXI™** Topical Solution for Cats (imidacloprid + moxidectin)

Once-a-month topical solution for cats for the prevention of heartworm disease, kills adult fleas, is indicated for the treatment of flea infestations, as well as the treatment and control of ear mite infestations and intestinal parasite infections in cats and kittens 9 weeks of age and older and that weigh at least 2 lbs.

#### CAUTION-

Federal (U.S.A.) Law restricts this drug to use by or on the order of a licensed

#### DESCRIPTION:

IMOXI<sup>NI</sup> Topical Solution for Cats (10% imidacloprid + 1% moxidectin) is a colorless to yellow ready-to-use solution packaged in single-dose applicator tubes for topical treatment of cats. The formulation and dosage schedule are designed to provide a minimum of 4.5 mg/lb (10.0 mg/kg) imidacloprid and 0.45 mg/lb (1.0 mg/kg) moxidectin based on body weight.

Imidacloprid is a chloronicotinyl nitroguanidine insecticide. The chemical name of imidacloprid is 1-[6.Chloro-3-pyridinyl)methyl)-N-nitro-2-imidazolidinimine. Moxidectin is a semisynthetic macrocyclic lactone endectocide derived from the actinomycete *Streptomycetes cyaneogrissus noncyanogenus*. The chemical name of moxidectin is [6R, 22E, 25S(E)]-5-0-Demethyl-28-deoxy-25-(1,3-dimethyl-1-butenyl)-6,28-epoxy-23-(methoxyimino) milbemycin B.

MOXI™ Topical Solution for Cats is indicated for the prevention of heartworm disease caused by *Dirofilaria immitis*. IMOXI™ Topical Solution for Cats kills adult fleas (*Ctenocephalides felis*) and is indicated for the treatment of flea infestations. IMOXI™ Topical Solution for Cats is also indicated for the treatment and control of ear mite (Otodectes cynotis) infestations and the following intestinal parasites:

Intestinal Parasite		Intestinal Stage		
		Adult	Immature Adult	Fourth Stage Larvae
Hookworm Species	Ancylostoma tubaeforme	Х	Х	Х
Roundworm Species	Toxocara cati	Х		Х

#### WARNINGS:

Do not use on sick, debilitated, or underweight cats (see ADVERSE REACTIONS). Do not use on cats less than 9 weeks of age or less than 2 lbs. body weight.

#### HUMAN WARNINGS:

Not for human use. Keep out of the reach of children.

Children should not come in contact with the application site for 30 minutes after application.

minutes after application.

Causes eye irritation. Harmful if swallowed. Do not get in eyes or on clothing. Avoid contact with skin. Exposure to the product has been reported to cause headache; dizziness; and redness, burning, tingling, or numbness of the skin. Wash hands thoroughly with soap and warm water after handling. If contact with eyes occurs, hold eyelids open and flush with copious amounts of water for 15 minutes. If eye irritation develops or persists, contact a physician. If swallowed, call poison control center or physician immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or physician. People with known hypersensitivity to heavy alcohol imidadonid or moxidecting. with known hypersensitivity to benzyl alcohol, imidacloprid or moxidectin should administer the product with caution. In case of allergic reaction, contact a physician. If contact with skin or clothing occurs, take off contaminated clothing. Wash skin immediately with plenty of soap and water. Call a poison control center or physician for treatment advice.

The Safety Data Sheet (SDS) provides additional occupational safety information. To report suspected adverse drug events, for technical assistance or to obtain a copy of the SDS, contact Vetoquinol USA at 1-800-835-9496 or www.vetoguinolusa.com

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

# PRECAUTIONS:

Do not dispense dose applicator tubes without complete safety and administration information.

Avoid oral ingestion. Cats may experience hypersalivation, tremors, vomiting and decreased appetite if  $\text{IMOXI}^{\text{TM}}$  Topical Solution for Cats is inadvertently administered orally or through grooming/licking of the application site.

The safety of IMOXI^TM Topical Solution for Cats has not been established in breeding, pregnant, or lactating cats.

The effectiveness of IMOXI™ Topical Solution for Cats against heartworm infections (*D. immitis*) after bathing has not been evaluated in cats.

Use of this product in geriatric patients with subclinical conditions has not been adequately studied. Several otherwise healthy, thin geriatric cats experienced prolonged lethargy and sleepiness after using imidacloprid and moxidectin topical solution. (See ADVERSE REACTIONS).

# ADVERSE REACTIONS:

Field Study: Following treatment with imidacloprid and moxidectin topical solution or an active control, cat owners reported the following post-treatment

OBSERVATION	Imidacloprid and Moxidectin Topical Solution n=113	Active Control n=38
Lethargy (protracted sleeping, poorly responsive)	3 cats* (2.7%)	None observed
Behavioral changes (e.g., agitated, excessive grooming, hiding, pacing, spinning)	9 cats (8.0%)	1 cat (2.6%)
Discomfort (e.g., scratching, rubbing, head-shaking)	5 cats (4.4%)	None observed
Hypersalivation (within 1 hour after treatment)	3 cats (2.7%)	None observed
Polydipsia	3 cats (2.7%)	None observed
Coughing and gagging	1 cat (0.9%)	None observed

<sup>\*</sup>These three cats were from the same household and included one 13-yr-old cat in good health, one 15-yr-old FIV positive cat in good health, and one 15-yr-old, underweight cat in fair health. Lethargy was noted for 24 to 36 hrs after the first treatment only; one cat was unsteady at 48hrs. These cats were not on other

During another field study, a 16-year-old cat with renal disease slept in the same place without moving for two days following application. (See PRECAUTIONS).

Laboratory Effectiveness Studies: Imidacloprid and moxidectin topical Laboratory Erectiveness Studies: Imidacioprila and moxidectin topical solution was administered at the recommended dose to 215 cats in 20 effectiveness studies. One random-sourced cat exhibited signs consistent with either moxidectin toxicity or viral respiratory disease and died 26 hours after product application; necropsy findings were inconclusive as to the cause of death. A second cat that became ill 3 days after application of imidacloprid and moxidectin topical solution responded to treatment for respiratory infection and completed the study. A third cat became ill on day 3 and died with signs and lesions attributable to panleukopenia on day 7 after moxidectin application.

Post-Approval Experience: The following adverse events are based on post-approval adverse drug experience reporting. Not all adverse reactions are reported to FDA CVM. It is not always possible to reliably estimate the adverse event frequency or establish a causal relationship to product exposure using this data. The following adverse events in cats are listed in decreasing order of reporting frequency: hypersalivation, depression/lethargy, application site reactions (alopecia, pruritus, lesions, and erythema), decreased appetite, vomiting, hyperactivity, ataxia, trembling, and behavior disorder (hiding).

In some cases, death has been reported.

In humans, ocular and dermal irritation, nausea, numbness or tingling of the mouth and lips, anaphylaxis, pruritus, vomiting, and tongue/taste abnormalities have been reported following exposure to imidacloprid and moxidectin topical

To report suspected adverse drug events, for technical assistance or to obtain a copy of the SDS, contact Vetoquinol USA at 1-800-835- 9496 or www.vetoquinolusa.com.

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

### DOSAGE AND ADMINISTRATION:

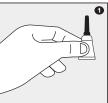
The recommended minimum dose is 4.5 mg/lb (10.0 mg/kg) imidacloprid and 0.45 mg/lb (1.0 mg/kg) moxidectin, once a month, by topical administration.

Do not apply to irritated skin.

Remove one dose applicator tube from the package. As specified in the following table, administer the entire contents of the IMOXI™ Topical Solution for Cats tube that correctly corresponds with the body weight of the cat.

Cat (lbs.)	Volume (mL)	Imidacloprid (mg)	Moxidectin (mg)
2-5	0.23	23	2.3
5.1-9	0.4	40	4
9.1-18*	0.8	80	8

\* Cats over 18 lbs. should be treated with the appropriate combination of IMOXI<sup>TM</sup> Topical Solution for Cats tubes.





- 2. While holding the Twist\*N\*GoTM tube in an upright position, twist dispensing tip clockwise about  $\frac{1}{2}$  turn to break the tube's seal. Remove the cap from the
- 3. Part the hair on the back of the cat's neck at the base of the head, until the skin is visible





4. Place the tip of the tube on the skin and apply the entire contents directly on the exposed skin. Lift the tube away from the skin before releasing pressure on

Do not get this product in the cat's mouth or eyes or allow the cat to lick the application site for 30 minutes. Treatment at the base of the head will minimize the opportunity for ingestion by grooming. In households with multiple pets, keep animals separated to prevent licking of the application site.

Stiff, matted hair or a damp, oily appearance of the hair may be observed at the application site on some cats. This is temporary and does not affect the safety and effectiveness of the product.

Heartworm Prevention: For prevention of heartworm disease, IMOXI™ Topical Solution for Cats should be administered at one-month intervals. IMOXI™ Topical Solution for Cats may be administered year-around or at a minimum should start one month before the first expected exposure to minimum should said the infinite before the lists expected exposure to mosquitoes and should continue at monthly intervals until one month after the last exposure to mosquitoes. If a dose is missed and a 30-day interval between doses is exceeded, administer IMOXI<sup>M</sup> Topical Solution for Cats immediately and resume the monthly dosing schedule. When replacing another heartworm preventative product in a heartworm prevention program, the first treatment with IMOXI<sup>TM</sup> Topical Solution for Cats should be given within one month of the last dose of the former medication. At the discretion of the veterinarian, cats last dose of the Information in the description in the Vetermanan, cars older than 6 months of age may be tested to determine the presence of existing heartworm infection before treatment with IMOXI™ Topical Solution for Cats. (See ADVERSE REACTIONS – Post-Approval Experience).

Flea Treatment: For the treatment of flea infestations, IMOXI™ Topical Solution for Cats should be administered at one-month intervals. If the cat is already infested with fleas when the first dose of IMOXI™ Topical Solution for Cats is administered, adult fleas on the cat will be killed. However, re-infestation from the emergence of pre-existing pupae in the environment may continue to occur for six weeks or longer after treatment is initiated. Cats treated with imidacloprid, including those with pre-existing flea allergy dermatitis, have shown clinical improvement as a direct result of elimination of fleas from the

Ear Mite Treatment: For the treatment of ear mites (Otodectes cynotis), IMOXI™ Topical Solution for Cats should be administered once as a single topical dose. Monthly use of IMOXI™ Topical Solution for Cats will control any subsequent ear mitle infestations.

Intestinal Nematode Treatment: For the treatment and control of intestinal hookworm infections caused by *Ancylostoma tubaeforme* (adults, immature adults and fourth stage larvae) and roundworm infections caused by *Toxocara cati* (adults and fourth stage larvae), IMOXI™ Topical Solution for Cats should be administered once as a single topical dose.

#### ANIMAL SAFETY:

Studies in Kittens: Imidacloprid and moxidectin topical solution was topically applied at 0, 1, 3, and 5X the maximum dose to 48 healthy 9-week-old kittens on days 0, 28, and 56. Lethargy was observed in 1 kitten from the 3X group and 1 from the 5X group on the day after initial treatment; the kitten from the 3X group was also disoriented and ataxic. One kitten from the 3X group had a slow pupillary light response two days after treatment and one had tremors the day after treatment. Hypersalivation was seen in one kitten from the 5X group approximately six hours post-treatment. One kitten from the 3X group was scratching at the treatment site 2 days after treatment. Slight cough was noted scratching at the rearrient size 2 days after treatment. Signific cough was noted in 7 different kittens (2-0X, 2-1X, and 3-5X) during the 13-day period following the first treatment. Histopathology showed granulomatous inflammation at the treatment site in three 1X kittens. Causal relationship to the drug could not be determined. Pulmonary inflammation (1-5X) and lymphoid hyperplasia (2-1X, 4-3X) were seen in treated kittens. In a second study, imidacloprid and moxidectin topical solution was topically applied at 0, 1.7, 5.2 and 8.7X the maximum dose to 48 healthy 9-week-old kittens every two weeks for 6 doses. One kitten in the 8.7X group apparently ingested an unknown amount of the drug and developed the following clinical signs prior to euthanasia: mydriasis, salivation, depression, vomiting, unsteadiness, rapid to slow to difficult breathing, poor pupillary response, generalized tremors, inability to move, and nystagmus. Two kittens in the 5.2X group developed mydriasis, salivation, depression, squinting, and poor appetite. A kitten in the 1.7X group developed

Dose Tolerance Study: Eight healthy juvenile cats were topically dosed with a single application of imidacloprid and moxidectin topical solution at 10 times the recommended dose volume. Mild, transient hypersalivation occurred in two of

Oral Study in Cats: The oral safety of imidacloprid and moxidectin topical Oral study in Cats: The oral safety of impostophic and moxidectin topical solution was tested in case of accidental oral ingestion. The maximum topical dose was orally administered to twelve healthy 9-week-old kittens. Hypersalivation (8 of 12 kittens) and vomiting (12 of 12 kittens) were observed immediately post-treatment. Tremors developed in one kitten within 1 hour resolving without treatment within the next hour. All 12 kittens were either anorexic or had decreased appetite for at least 1 day following treatment. In 3 kittens, the anorexia or decreased appetite continued into the second week following treatment. There was a post-treatment loss of body weight in treated wittens compared to control kittens. In a pilot safety study using kittens younger in age and lighter in weight than allowed by product labeling, an 8-week-old kitten weighing 0.6 kg orally received 2X of the label topical dose (0.46 mL/kg). Immediately after dosing, it vomited, had labored breathing and slight tremors. Within 4 hours, it was normal, but was found dead on day 6. Necropsy could not determine the survey of death. determine the cause of death.

Study in Heartworm Positive Cats: Young adult cats were inoculated subcutaneously with third-stage *D. immitis* larvae. At 243-245 days post-infection, immunoserology and echocardiography were performed to identify cats with adult heartworm burdens similar to naturally-acquired infections. Two groups were treated topically with either imidacloprid and moxidectin topical solution at the label dose or placebo, once every 28 days, for three consecutive treatments. A third group was treated topically, once, with imidacloprid and moxidectin topical solution at 5X the label dose. Sporadic vomiting and labored breathing related to heartworm burden were observed in the treatment and control groups. There was no fifteence between treatment the treatment and control groups. There was no difference between treatment groups in the numbers of adult *D. immitis* recovered at study conclusion. No adverse reactions were associated with the topical application of imidacloprid and moxidectin topical solution to experimentally heartworm-infected cats.

## STORAGE INFORMATION:

Store at temperatures between 20°C (68°F) and 25°C (77°F), avoiding excess heat or cold.

HOW SUPPLIED: Applications Per Package 3 x 0.23 mL tubes

Approved by FDA under ANADA # 200-638

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