

#### ON THE LOOKOUT

Routine diagnostic tests can miss *Otodectes cynotis* infestations, but safe treatment is readily available for both dogs and cats.

## PARASITOLOGY

# Ear Mites: Uncovering, Treating, and Preventing Infestations

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Although most often identified in young cats, ear mites (*Otodectes cynotis*) are a common cause of otitis externa and pruritus in cats and dogs worldwide. Most veterinary healthcare team members are familiar with the copious dark, granular otic discharge of newly adopted kittens that indicates mites are likely to be found on otoscopic or microscopic examination. Some patients with ectopic mites present with generalized alopecia and pruritus similar to flea allergy dermatitis.<sup>1</sup> Although under-recognized, ear mite infestations can be readily addressed. Being aware of this common parasite is a key first step.

## BIOLOGY

### Life Cycle

Female *O. cynotis* mites cement developing eggs to the epidermal lining of the ear canal; larvae hatch in a few days and molt through 2 nymphal stages to the next generation of adults. Ear mites feed on epithelial cells, exudate, and tissue fluid but do not burrow. The entire life cycle takes less than 3 weeks. Infestation follows direct contact and commonly occurs from dam to offspring in the neonatal period. Although documented, off-host mite survival is considered limited.<sup>2,3</sup>

### Morphology

Adult *O. cynotis* are large mites; at approximately 400  $\mu\text{m}$ , females may be visible without magnification. When examined by microscopy, mites are usually active and a large, single egg is often present within females (FIGURE 1A). The first 2 pairs of legs of the female end in caruncles (suckers) attached to very short stalks; the fourth pair of legs on the female is vestigial. Males (FIGURE 1B) are slightly smaller than females and have distinct copulatory structures on the ventral surface. All legs on male *O. cynotis* end in suckers attached to short stalks.<sup>4</sup>

### Epidemiology

Prevalence estimates vary widely based on the population examined and the sensitivity of the diagnostic method used. A survey of pet cats from 7 European countries found ear mites were the most common ectoparasite, present in 17.4% of cats, and more commonly recovered from cats than fleas.<sup>5</sup> In a survey in northern Italy, over half of the free-roaming cats examined had clinical evidence of otitis externa and *O. cynotis* was found in the majority.<sup>6</sup> Infested animals with asymptomatic infestations serve as important reservoirs.



In general, ear mites are most common in young, free-roaming cats and dogs and in pets with outdoor access, although as many as 25% of pet cats and 6.7% of pet dogs are infested.<sup>7-10</sup> Although mites are most commonly identified in kittens, age-related differences in ear mite prevalence are not consistent and adult cats are frequently infested. Similarly, breed, sex, and age have not been associated with increased infestation prevalence in dogs.<sup>11</sup> Ferrets and wild canids, especially foxes, are commonly infested.<sup>12,13</sup>

## Transmission

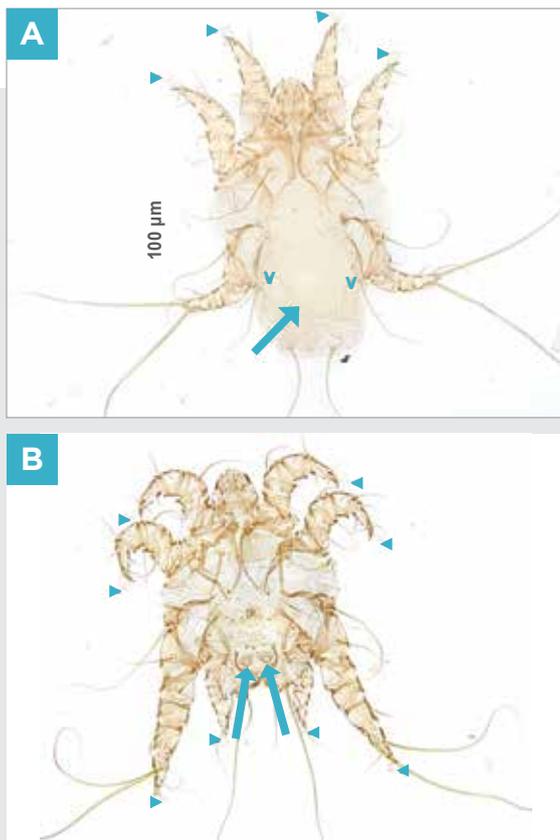
Because mite survival off-host is limited, direct contact with an infested animal is the most likely mode of transmission.<sup>3,4</sup> Mites are transmitted among all age classes and between infested dams and nursing young. Transmission between cats, dogs, and ferrets is also possible.<sup>2</sup> As many as 10% of cats harbor subclinical infestations, serving as a source for future

infestations.<sup>9,14</sup> *O cynotis* does not pose a major zoonotic risk; however, reports of human infestations exist, as do cases of dermatitis following close contact with an infested animal.<sup>2,12</sup>

## CLINICAL SIGNS

Animals with *O cynotis* infestations present clinically normal or with otic pruritus that is usually bilateral.<sup>7</sup> Magnitude of clinical signs appears to be independent of the number of mites. Cats may have significant infestations with minimal pruritus, whereas dogs are more likely to be pruritic.<sup>1</sup> Symptomatic animals display varying degrees of irritation and pruritus associated with head shaking, head tilt, and circling; a pinnal-pedal reflex can be elicited when the infested ear canal is massaged.<sup>15</sup>

A dark, “coffee ground” otic discharge is a classic presentation (**FIGURE 2**), although the color and



**FIGURE 1. (A)** Adult female *Otodectes cynotis* with large egg evident (**arrow**). The first 2 pairs of legs have suckers at the end of short stalks (**arrowheads**); the fourth pair of legs is vestigial (**V**). (**B**) Adult male *O cynotis* with copulatory structures (**arrows**) evident. All 4 pairs of legs have suckers (**arrowheads**) at the end of short stalks.



**FIGURE 2. (A)** Otoscopic view of external acoustic meatus of a cat infested with ear mites showing the characteristic dark, granular, “coffee ground” appearance of the discharge. (**B**) A moderate number of mites (**arrow**) in an erythematous vertical otic canal at the level of the intertragic incisure. Mite populations may be reduced when inflammation is severe.

consistency vary, and some infested cats have scant cerumen.<sup>12</sup> Severely infested animals or those with hypersensitivity reactions can present with self-excoriation and dermal trauma. Hematomas and secondary infections are not uncommon.<sup>12</sup> Less common clinical presentations include miliary dermatitis of the head, feet, or tail due to ectopic mites.<sup>1,12</sup> Left untreated, infested animals, particularly cats, may become emaciated or develop neurologic signs.<sup>15</sup>

Ear mites are a common cause of otitis externa, with as many as 85% of feline cases and 50% of canine cases reportedly associated with *O cynotis* infestation.<sup>16</sup> Additionally, chronic, uncontrolled *O cynotis* infestation and the resultant ceruminous gland hyperplasia have been linked with development of ceruminous gland tumors in some animals.<sup>13,17</sup> A diffuse hypersensitivity reaction resembling flea allergy dermatitis, in which pets present with widespread pruritus, excessive grooming, and alopecia, has been described as associated with ectopic ear mites in some patients.<sup>1,15</sup>

Pathology of *O cynotis* infestation develops from inflammation caused by mite feeding and includes accumulation of moderate to excessive dark brown ceruminous exudate.<sup>4</sup> Some infested pets display minimal pathology even though the presence of mites is confirmed.<sup>9</sup> When pathologic changes are present, the epithelium of the ear canal is usually erythematous, hyperplastic, and hyperkeratotic. Histopathologic examination shows hyperplastic sebaceous and ceruminous glands, dilated blood vessels, and macrophage and mast cell infiltrates.<sup>1,2</sup> When treatment is delayed, secondary bacterial and fungal infections can develop; *Staphylococcus* and *Malassezia* species are most commonly identified.<sup>18</sup>



**FIGURE 3.** Ooscopic examination can directly identify mites but is less sensitive than methods that collect cerumen and debris from both ears for direct microscopic examination.

## DIAGNOSIS

Mites can be visualized directly in the ear canal, crawling on the surface of otic discharge, during routine otoscopic examination (FIGURE 3). However, relying on this method alone misses many infestations.<sup>9</sup> In one comparison study, one-third of infested cats were not diagnosed when examined by otoscope alone.<sup>19</sup> Infestations are more likely to be detected by microscopic examination of samples collected from both ears.<sup>7,19</sup> Although otic discharge, pruritus, acne-like lesions, and head shaking are present in some infested pets, others will have large numbers of mites with scant evidence of pruritus or discharge, and the ears of some animals that harbor *O cynotis* appear normal.<sup>9</sup>

To examine for ear mites, material from both ears can be collected with a cotton-tipped swab lightly coated in mineral oil and then transferred to a microscope slide (FIGURE 4). Research on ear mite prevalence has

**TABLE 1** Products for Treating *Otodectes cynotis* Infestations in Cats<sup>a</sup>

PRODUCT	ROUTE	REGIMEN
Ivermectin (Acarexx)	Otic	Once in each ear; repeat in 2 weeks <sup>3</sup>
Milbemycin oxime (MilbeMite)	Otic	Once in each ear; repeat in 2 weeks <sup>3</sup>
Imidacloprid + moxidectin (Advantage Multi for Cats)	Transdermal	Once to back of neck; repeat monthly as needed
Selamectin (Revolution)	Transdermal	Once to back of neck; repeat monthly as needed
Moxidectin + fluralaner (Bravecto Plus)	Transdermal	Once to back of neck; repeat every 8 weeks as needed
Selamectin + sarolaner (Revolution Plus)	Transdermal	Once to back of neck; repeat monthly as needed
Fluralaner (Bravecto) <sup>b</sup>	Transdermal	Once to back of neck; repeat every 12 weeks as needed <sup>20,21</sup>

All products listed are FDA (Food and Drug Administration)-approved but may not be approved for treatment of ear mites in cats.

<sup>a</sup>Products effective for treatment would also be expected to support prevention of reinfestation.

<sup>b</sup>Not FDA-approved for treatment of *O cynotis* in cats, but cited publications support efficacy.



**FIGURE 4.** Although it misses some infestations, a cotton-tipped swab lightly coated in mineral oil can be used to collect cerumen for examination. Both ears should be evaluated.

shown that, when present in low numbers, mites can be missed by swabbing alone.<sup>7</sup> Curettage to collect cerumen or flushing the external ear canal with a small amount of mineral oil increases sensitivity of detection but is often impractical in a clinical setting.<sup>7,19</sup> Response to treatment—resolution of either otic pruritus or, in the case of hypersensitivity, diffuse allergic pruritus—can be used to support a clinical diagnosis if ear mites are not recovered.<sup>1</sup>

## TREATMENT

Several safe, effective ear mite treatments are available for both cats (**TABLE 1**) and dogs (**TABLE 2**). Macrocytic lactones are label-approved to treat ear mites in cats or dogs, including transdermal, systemic formulations of moxidectin and selamectin and otic formulations of ivermectin and milbemycin oxime.<sup>22,28</sup> Systemic isoxazolines (afoxolaner, fluralaner, lotilaner,

sarolaner) are also effective and can be used alone or in combination with a macrocyclic lactone.<sup>20,21,25-27,29</sup> Use of systemic products targets mites outside the ear canal and can limit the diffuse hypersensitivity reaction seen in some patients.

Historically, other treatments were commonly used to clear ear mite infestations. Mineral oil applied to the ear canal reduces mite populations; however, many repeated treatments are needed, aggressive cleaning can exacerbate otitis or cause trauma, and an oily residue can be left on the animal.<sup>2</sup> Other otic formulations have been suggested, including preparations containing pesticides, but insufficient evidence supports their use and adverse events are reported.<sup>22</sup> Prior to the development of safer and more effective treatments, ear mites were sometimes managed by administering large animal preparations of macrocyclic lactones off-label. This approach has safety concerns and is no longer necessary or recommended.

Common sequelae of infestation, such as ear discharge and inflammation, should be addressed to support resolution of clinical signs. Although not necessarily required per label, the debris within the ear canals can be cleared away with a mild ceruminolytic agent formulated for otic use before initial treatment to ensure proper contact with an otic acaricide, address the clinical signs, and relieve patient discomfort. Cleaning the ears may need to be repeated if debris persists or recurs, but care should be taken to avoid irritating the ear canal.<sup>30</sup> When present, secondary bacterial or fungal infections should be treated concurrently with acaricide administration.<sup>18</sup>

Reinfestation following treatment readily occurs.<sup>31</sup> Regardless of clinical signs, all pets in the home that

**TABLE 2** Products for Treating *Otodectes cynotis* Infestations in Dogs<sup>a</sup>

TREATMENT	ROUTE	REGIMEN
Selamectin (Revolution)	Transdermal	Once to back of neck; repeat monthly as needed
Imidacloprid + moxidectin (Advantage Multi for Dogs) <sup>b</sup>	Transdermal	Once to back of neck; repeat monthly as needed <sup>22,23</sup>
Milbemycin oxime (MilbeMite) <sup>b</sup>	Otic	Once (0.5 mL, 2 tubes) in each ear; repeat in 2 weeks <sup>24</sup>
Milbemycin oxime (Interceptor) <sup>b</sup>	Oral	Monthly as needed <sup>24</sup>
Afoxolaner (NexGard) <sup>b</sup>	Oral	Monthly as needed <sup>25,26</sup>
Fluralaner (Bravecto) <sup>b</sup>	Transdermal, Oral	Every 12 weeks to back of neck or orally as needed <sup>20</sup>
Sarolaner (Simparica) <sup>b</sup>	Oral	Monthly as needed <sup>27</sup>

All products listed are FDA (Food and Drug Administration)-approved but may not be approved for treatment of ear mites in dogs.

<sup>a</sup>Products effective for treatment would also be expected to support prevention of reinfestation.

<sup>b</sup>Not FDA-approved for treatment of *O. cynotis* in dogs, but cited publications support efficacy.


**(florfenicol, terbinafine, mometasone furoate)**  
**Otic Solution**

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

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

**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*).

**DOSE AND ADMINISTRATION:**  
**Shake before use.**
**CLARO® should be administered by veterinary personnel.**  
 Administer one dose (1 dropperette) 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.
- Remove single dose dropperette from the package.
- While holding the dropperette in an upright position, remove the cap from the dropperette.
- Turn the cap over and push the other end of the cap onto the tip of the dropperette.
- Twist the cap to break the seal and then remove cap from the dropperette.
- Screw the applicator nozzle onto the dropperette.
- Insert the tapered tip of the dropperette into the affected external ear canal and squeeze to instill the entire contents (1 mL) into the affected ear.
- Gently massage the base of the ear to allow distribution of the solution.
- Repeat with other ear as prescribed.

Cleaning the ear after dosing may affect product effectiveness.

**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.

**WARNINGS:**
**Human Warnings:** Not for use in humans. Keep this and all drugs out of reach of children. 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. Reevaluate 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 (see **ANIMAL SAFETY**).

 Use with caution in dogs with impaired hepatic function (see **ANIMAL SAFETY**).

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 (see **EFFECTIVENESS**), 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) or 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>.

**PHARMACOLOGY:**

CLARO® Otic Solution is a fixed combination of three active substances: florfenicol (antibacterial), terbinafine (antifungal), and mometasone furoate (steroidal anti-inflammatory). Florfenicol is a bacteriostatic antibiotic which acts by inhibiting protein synthesis. Terbinafine is an antifungal which selectively inhibits the early synthesis of ergosterol. Mometasone furoate is a glucocorticosteroid with anti-inflammatory activity.

**MICROBIOLOGY:**

 The compatibility and additive effect of each of the components in CLARO® solution was demonstrated in a component effectiveness and non-interference study. An *in vitro* study of organisms collected from clinical cases of otitis externa in dogs enrolled in the clinical effectiveness study determined that florfenicol and terbinafine hydrochloride inhibit the growth of bacteria and yeast commonly associated with otitis externa in dogs. No consistent synergistic or antagonistic effect of the two antimicrobials was demonstrated. The addition of mometasone furoate to the combination did not impair antimicrobial activity to any clinically significant extent.

 In a field study (see **EFFECTIVENESS**), at least 10 isolates from successfully treated cases were obtained for *S. pseudintermedius* and *M. pachydermatis*.

**EFFECTIVENESS:**

In a well-controlled, double-masked field study, CLARO® was evaluated against a vehicle control in 221 dogs with otitis externa. One hundred and forty six dogs were treated with CLARO® and 75 dogs were treated with the vehicle control. All dogs were evaluated for safety. Treatment (1 mL) was administered once on Day 0 to the affected ear(s). Prior to treatment, the ear(s) was cleaned with saline. The dogs were evaluated on Days 0, 7, 14, and 30. Blood work and urinalysis were obtained on Day 0 pre-treatment and Day 30 at study completion. Four clinical signs associated with otitis externa were evaluated: erythema, exudate, swelling, and ulceration. Success was based on clinical improvement at Day 30. Of the 183 dogs included in the effectiveness evaluation, 72.5% of dogs administered CLARO® solution were successfully treated, compared to 11.1% of the dogs in the vehicle-control group (p&lt;0.0001).

**ANIMAL SAFETY:**

In a target animal safety study, CLARO® was administered aurally to 12-week-old Beagle puppies (4 dogs/sex/group) at 0X, 1X, 3X, and 5X the recommended dose once every 2 weeks for a total dosing period of 28 days (3 times the treatment duration). No clinically relevant treatment-related findings were noted in hearing tests, body weight, weight gain, or food consumption. CLARO® administration was associated with post-treatment ear wetness or clear aural exudate, increased absolute neutrophil count, decreased absolute lymphocyte and eosinophil counts, suppression of the adrenal cortical response to ACTH-stimulation, decreased adrenal weight and atrophy of the adrenal cortex, increased liver weight with hepatocellular enlargement/cytoplasmic change, and decreased thymus weight. Other potentially treatment-related effects included mild changes to AST, total protein, inorganic phosphorus, creatinine, and calcium.

**STORAGE INFORMATION:**

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

**HOW SUPPLIED:**

CLARO® solution is supplied in a single-use dropperette in a blister. Each dropperette contains one 1 mL dose.

CLARO® is available in cartons of two, ten, or twenty dropperettes.

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 NADA 141-440, Approved by FDA  
 LV1802



can be infested with ear mites (cats, dogs, ferrets) should be treated. Repeated monthly treatment with persistent acaricides is ideal; subclinical infestations that go untreated are the primary cause of reinfestation. Many products with efficacy against ear mites (macrocylic lactones and isoxazolines) have other benefits supporting their use in practice, including efficacy against fleas, ticks, intestinal parasites, and heartworms.

## CONCLUSION

Although common in free-roaming animals,<sup>9,32</sup> the true prevalence of *O. cynotis* in cats and dogs across the United States is not fully understood. Routine diagnostic tests can miss infestations, meaning ear mites are likely under-diagnosed. Careful diagnostic evaluation and routine use of acaricides—including transdermal macrocyclic lactones and isoxazolines commonly used for flea, tick, and internal parasite control—help mitigate infestation with this common parasite. **TVP**

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## Susan Little

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## Kathryn Duncan

Dr. Duncan is a graduate of the University of Tennessee's College of Veterinary Medicine and the Boehringer Ingelheim resident in veterinary parasitology at OSU through the National Center for Veterinary Parasitology. Her most recent publications discuss ticks of importance to dogs and cats and intestinal parasites detected from dogs attending dog parks. Her current research interests include ticks and tick-borne diseases, heartworm disease, and diagnosis and treatment of intestinal parasites of domestic animals.



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

**BRIEF SUMMARY:** Before using IMOXI™ Topical Solution for Dogs (imidacloprid + moxidectin) or IMOXI™ Topical Solution for Cats (imidacloprid + moxidectin), please consult the product insert, a summary of which follows:

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

#### IMOXI™ Topical Solution for 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 application sites for two (2) hours after application.**
- (See Contraindications, Warnings, Human Warnings, and Adverse Reactions, for more information.)

#### INDICATIONS:

**IMOXI™ 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 (*Ctenocephalides felis*). IMOXI™ Topical Solution for Dogs is indicated for the treatment and control of sarcoptic mange caused by *Sarcoptes scabiei* var. *canis*. IMOXI™ Topical Solution for Dogs is also indicated for the treatment and control of the following intestinal parasites species: Hookworms (*Ancylostoma caninum*) (*Uncinaria stenocephala*), Roundworms (*Toxocara canis*) (*Toxascaris leonina*) and Whipworms (*Trichuris vulpis*).

**IMOXI™ 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 intestinal parasites species Hookworm (*Ancylostoma tubaeforme*) and Roundworm (*Toxocara cati*).

#### CONTRAINDICATIONS:

Do not administer this product orally. (See WARNINGS)  
Do not use the Dog product (containing 2.5% moxidectin) on cats.

#### WARNINGS:

**IMOXI™ Topical Solution for Dogs:** 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,<sup>a</sup> the signs may be more severe and may include coma and death.<sup>b</sup>

<sup>a</sup> 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>b</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.

**IMOXI™ Topical Solution for Cats:** Do not use on sick, debilitated, or underweight cats. 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. Dogs: Children should not come in contact with the application sites for two (2) hours after application. Cats: Children should not come into contact with the application site for 30 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 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.

#### PRECAUTIONS:

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.

Cats may experience hypersalivation, tremors, vomiting and decreased appetite if IMOXI™ Topical Solution for Cats is inadvertently administered orally or through grooming/licking of the application site. The safety of IMOXI™ 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.

#### ADVERSE REACTIONS:

**Heartworm-Negative Dogs:** The most common adverse reactions observed during field studies were pruritus, residue, medicinal odor, lethargy, inappetence and hyperactivity.

#### Heartworm-Positive Dogs:

The most common adverse reactions observed during field studies were cough, lethargy, vomiting, diarrhea (including hemorrhagic), and inappetence.

#### ADVERSE REACTIONS - Cats:

The most common adverse reactions observed during field studies were lethargy, behavioral changes, discomfort, hypersalivation, polydipsia and coughing and gagging.

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.

IMOXI™ Topical Solution for Dogs Approved by FDA under ANADA # 200-615

IMOXI™ Topical Solution for Cats Approved by FDA under ANADA # 200-638

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