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

DESCRIPTION: CLARO™ Otic Solution is a fixed combination of florfenicol for antibacterial, terbinafine for antifungal, and mometasone furoate for anti-inflammatory activity. Florfenicol is an antibacterial which selectively inhibits the early synthesis of the bacterial cell wall. Terbinafine is an antifungal which selectively inhibits the fungal cell wall. Mometasone furoate is a glucocorticosteroid with anti-inflammatory activity.

INDICATIONS: CLARO™ Otic Solution is indicated for the treatment of otitis externa in dogs associated with susceptible strains of yeast (Malassezia pachydermatis) and bacteria (Staphylococcus pseudintermedius) in the external ear canal in dogs.

Dosage and Administration:

Shake before use. CLARO™ Otic Solution should be administered by veterinary personnel.

Administer one dose (1 dropperette) per affected ear. The duration of effect should last 30 days.

1. Clean and dry the external ear canal before administering the product.

2. Verify the tympanic membrane is intact prior to administration.

3. Remove single dose dropperette from the package.

4. While holding the dropperette in an upright position, remove the cap from the dropperette.

5. Turn the cap over and push the other end of the cap onto the tip of the dropperette.

6. Twist the cap to break the seal and then remove cap from the dropperette.

7. Hold the ear(s) and position the affected ear(s) so that the dropperette tip is centered in the external ear canal.

8. 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.

9. Gently massage the base of the ear to allow distribution of the solution.

10. Repeat with other ear as prescribed.

Chaining the car after dosing may affect product effectiveness.

CONTRAINDICATIONS:

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

CLARO™ Otic Solution is contraindicated in dogs with known or suspected hypersensitivity to florfenicol, terbinafine hydrochloride, or mometasone furoate.

WARNINGS:

Hypersensitivity: Not for use in humans. Keep this and all drugs out of reach of children. In case of accidental ingestion by humans, contact your 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 the 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 prior to administering the product. Repeated use of the dropper head or signs of otic erythema should be monitored 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 PRECAUTIONS).

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 a copy of the Safety Data Sheet (SDS) or for technical assistance, contact Bayer HealthCare LLC at 1-800-422-9674.

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 (enantioenriched), terbinafine (enantioenriched), and mometasone furoate (enantioenriched). Each of these components is selectively active against its designated target, which allows anti-inflammatory activity.

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 resulted 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 Staphylococcus and Strep. pyogenes.

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, 72.9% of dogs administered CLARO™ solution were successfully treated, compared to 17.1% of the dogs in the vehicle-control group (p<0.0001).

ANIMAL SAFETY:

In a target animal safety study, CLARO™ was administered orally to 12-week-old Beagle puppies (n=16/group) for 16, 18, and 32 weeks. No adverse clinical signs were observed in any of the groups during the treatment or post-treatment period. No clinically relevant treatment-related findings were noted in blood chemistry, body weight, weight gain, or food consumption. CLARO™ administration was associated with post-treatment decreased eosinophil and increased neutrophil counts, increased absolute lymphocyte count, decreased absolute lymphocyte and eosinophil counts, suppression of the adrenal cortical response to ACTH stimulation, decreased adrenal weight and adrenocortical activity, increased liver weight with hepatocellular enlargement/cytoplasmic change, and decreased thymus weight. Other parameters demonstrated included mild changes to AST, total protein, inorganic phosphorus, creatinine, and calcium.

STORAGE INFORMATION:


HOW SUPPLIED:

CLARO™ Otic 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.

Bayer

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Introducing CLARO™
(florfenicol, terbinafine, mometasone furoate)
Otic Solution

the only veterinarian-administered,
single-dose regimen for canine otitis externa.

CAUTION: Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian. CONTRAINDICATIONS: Do not use in dogs with known tympanic membrane perforation. CLARO™ is contraindicated in dogs with known or suspected hypersensitivity to florfenicol, terbinafine hydrochloride, or mometasone furoate.
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<th>FRONTLINE GOLD BRAND PRODUCTS</th>
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<td>STARTS KILLING FLEAS IN 30 MINUTES ON DOGS (FRONTLINE Gold for Dogs only)*,1</td>
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* When infested 48 hours after application.

1 Data on file at Merial
2 Data on file at Merial
3 Data on file at Merial
Approval pending in the state of Massachusetts.
Meet The Speakers

Anesthesia
Ralph Harvey, DVM, MS, DACVAA
University of Tennessee
Knoxville, TN

Avian Medicine
*Julia Whittington, DVM
University of Illinois
Urbana, IL

Behavior
E'Lise Christensen, DVM, DACVB
Veterinary Behavior Consultations of NYC and CO
Castle Rock, CO

**Sagi Denenberg, DVM, DACVB, DECAWBM, MACVSc, MRCVS
Langford, Bristol

*Gary Landsberg, DVM, DACVB, DECAWBM
North Toronto Veterinary Behaviour Specialty Clinic
Thornhill, Canada

Canine Sports Medicine and Rehabilitation
Robert Gillette, DVM, MSE, DACVS/SMR
Red Bank Veterinary Hospital
Tinton Falls, NJ

Cardiology
Whit Church, DVM, DACVIM
Desert Veterinary Medical Specialists
Gilbert, AZ

Clinical Pathology
Craig Thompson, DVM, DACVP
Purdue University
West Lafayette, IN

Clinical Pharmacology
Melissa Clark, DVM, PhD, DACVC
Animal Medical Center
New York, NY

Lauren Trepanier, DVM, PhD, DACVC
University of Wisconsin
Madison, WI

Critical Care
Nathan Peterson, DVM, DACVECC
VCA West Los Angeles Animal Hospital
Los Angeles, CA

*Kari Santoro Beer, DVM, DACVECC
Michigan State University
East Lansing, MI

Dentistry
*Barden Greenfield, DVM, DAVDC
MidSouth Veterinary Dental Referrals
Cordova, TN

Allison Woody, DVM
San Diego Veterinary Dentistry
San Diego, CA

Dermatology
*Jeanne Budgin, DVM, DACVD
Riverdale Veterinary Dermatology
Riverdale, NJ

Allison Kirby, DVM, DACVD
Animal Dermatology Clinic
Indianapolis, IN

James Noxon, DVM, DACVIM
Iowa State University
Ames, IA

Dvm360 Leadership Challenge
Brendan Howard
Business Channel Director

Kristi Reimer
News Channel Director

Portia Stewart
Team Channel Director

Mindy Valcarcel
Medicine Channel Director

Endocrinology
*Ellen Behrend, VMD, PhD, DACVIM
Auburn University
Auburn, AL

Exotic Animal Medicine
*Julia Whittington, DVM
University of Illinois
Urbana, IL

Feline Medicine
Steven Bailey, DVM, DABVP
Exclusively Cats Veterinary Hospital
Waterford, MI

Robin Downing, DVM, DAAPM, DACVS/SMR, CVPP, CCPP
The Downing Center for Animal Pain Management
Windsor, CO

Margie Scherk, DVM, DABVP
Vancouver, Canada

Gastrointestinal Medicine
*Scott Owens, DVM, MS, DACVIM
MedVet Indianapolis
Carmel, IN

Kenneth Simpson, BVM&S, PhD, DACVIM, DECVIM
Cornell University
Ithaca, NY

Katherine Tolbert, DVM, PhD, DACVIM
University of Tennessee
Knoxville, TN

Imaging
Chelsea Kunst, DVM, DACVR
California Veterinary Specialists
Murrieta, CA

Anthony Pease, DVM, MS, DACVR
Michigan State University
East Lansing, MI

Kathy Spaulding, DVM, DACVR
Texas A&M University
College Station, TX

Sarena Sunico, DVM, DACVR
Veterinary Specialty Hospital San Diego
San Diego, CA

Low-Stress, Pet-Friendly Practice
Marty Becker, DVM
North Idaho Animal Hospital
Sandpoint, ID

Mikkel Becker, CPDT
VetStreet.com
Seattle, WA

*Jonathan Bloom, DVM
Willowdale Animal Hospital
Ontario, Canada

Ralph Harvey, DVM, MS, DACVAA
University of Tennessee
Knoxville, TN

*Gary Landsberg, DVM, DACVB, DECAWBM
North Toronto Veterinary Behaviour Specialty Clinic
Thornhill, Canada

Neurology
*Heidi Barnes Heller, DVM, DACVIM
University of Wisconsin
Madison, WI

Nutrition
*Martha Cline, DVM, DACVN
Red Bank Veterinary Hospital
Tinton Falls, NJ

*Participating in the Technician Program
**Online Collaborator
***Presenting a dvm360 Leadership Challenge Session
Meet The Speakers

**Oncology**
Sue Ettinger, DVM, DACVIM  
Dr. Sue Cancer Vet  
Tarrytown, NY

**Ophthalmology**
Rebecca Burwell, DVM, DACVO  
Eye Care for Animals  
Corte Madera, CA

Kicket Konrade, DVM, MS, DACVO  
Eye Care for Animals  
Pasadena, CA

*Reuben Merideth, DVM, DACVO  
Eye Care for Animals  
Tucson, AZ

Joanna Norman, DVM, DACVO  
Eye Care for Animals  
Avondale, AZ

Rustin Sturgeon, DVM, DACVO  
Eye Care for Animals  
Overland Park, KS

Neal Wasserman, DVM, DACVO  
Eye Care for Animals  
Wheeling, IL

**Orthopedics**
*David Dycus, DVM, MS, DACVS, CCRP  
Veterinary Orthopedic and Sports Medicine Group  
Annapolis Junction, MD

**Pain Management**
*Matthew Brunke, DVM, CCRP, CVPP, CVA  
North County Veterinary Referral Practice  
Glen Falls, NY

**Parasitology**
Lindsay Starkey, DVM, PhD, DACVM  
Auburn University  
Auburn, AL

**Practice Management**
***Brian Conrad, CVPM  
Meadow Hills Veterinary Center  
Kennewick, WA

Karen Felsted, CPA, MS, DVM, CVPM  
PantheraT Veterinary Management Consulting  
Dallas, TX

Eric Garcia  
Simply Done Tech Solutions  
Lutz, FL

Sheila Grosdidier, BS, RVT, PHR  
Veterinary Management Consultants  
Evergreen, CO

Bash Halow, LVT, CVPM  
Halow Tassava Consulting  
New York, NY

Laurie Hess, DVM, DABVP  
Veterinary Center for Birds and Exotics  
Bedford Hills, NY

**Soft Tissue Surgery**
Sara Colopy, DVM, PhD, DACVS  
University of Wisconsin  
Madison, WI

*Karen Tobias, DVM, DACVS  
University of Tennessee  
Knoxville, TN

**Shelter Medicine**
Philip Bushby, DVM, MS, DACVS  
Mississippi State University  
Mississippi State, MS

*Amanda Dykstra, DVM  
University of Tennessee  
Knoxville, TN

**Technician Program**
Vickie Byard, CVT, VTS (Dentistry), CVJ  
PetED Veterinary Education and Training  
Warminster, PA

Kristen Cooley, BA, CVT, VTS  
(Anesthesia/Analgesia)  
University of Wisconsin  
Madison, WI

Tasha McNerney, BS, CVT, CVPP, VTS  
(Anesthesia/Analgesia)  
Veterinary Anesthesia Nerds  
Glenside, PA

Oriana Scislowicz, BS, LVT  
CVCA – Cardiac Care for Pets  
Richmond, VA

**Veterinary Leadership**
Betsy Charles, DVM, MA  
Veterinary Leadership Institute and Western University of Health Sciences  
Pomona, CA

Caitlin DeWilde, DVM  
The Social DVM and Brentwood Animal Hospital  
Brentwood, MO

Sarah Wooten, DVM  
Sheep Draw Veterinary Hospital  
Greeley, CO

**Veterinary Hospice and Palliative Care**
*Mary Gardner, DVM  
Lap of Love  
Bandon, OR

**Urology**
Gregory Grauer, DVM, MS, DACVIM  
Kansas State University  
Manhattan, KS

**USDA/NVAP**
Scott Beutelschies, DVM  
USDA APHIS Veterinary Service  
Sacramento, CA

Jessica Coote, DVM  
USDA APHIS Veterinary Service  
Ontario, CA

Larry Rawson, DVM  
USDA APHIS Veterinary Service  
Joplin, MO

**Toxicology**
*Tim Evans, DVM, PhD, DACT, DABVT  
University of Missouri  
Columbia, MO

**Urology**
Gregory Grauer, DVM, MS, DACVIM  
Kansas State University  
Manhattan, KS

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Scott Beutelschies, DVM  
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