



# VMX 2021: Forward



We know you might still be learning to adapt to a world dominated by COVID-19—so are we. That is why the North American Veterinary Community (NAVC) has reimagined the annual Veterinary Meeting and Expo (VMX) to be available in a variety of online and interactive modes come January 2021.

The NAVC has an important role in paving the way forward for the veterinary community. More than ever, we believe in coming together to imagine new ways of thinking, learning, and connecting—both in person and virtually. In addition to offering traditional in-person attendance, the NAVC will be offering 3 ways to access VMX Virtual: OnDemand, Scheduled, and Interactive.

## VMX VIRTUAL OFFERINGS

- **VMX OnDemand** will feature recorded continuing education (CE) sessions. Attendees will be

able to access these sessions 24/7 from the start of VMX until April 16th. CE can be earned by answering quiz questions at the end of the recording with unlimited retakes to obtain a passing score.

- **VMX Scheduled Sessions** will require attendees to be present online during the premiere of a session, complete with a chat room and moderator. VMX Virtual scheduled sessions will be similar to traditional on-site sessions and will get logged into your record of participation. After the session premieres it will be available OnDemand, and CE can be earned by answering the quiz questions.
- **VMX Interactive** will be a scheduled session with interaction from the speaker virtually. Attendees will be able to participate in chat, polling with their colleagues, and submitting questions for the presenter, as well as earn CE. After the session airs it will be available OnDemand and CE can be earned by answering the quiz questions.

All of these redesigned ways to access the world's leading veterinary educational material will be available via our inaugural VMX Virtual platform. This platform presents the veterinary community with a way to experience the entirety of what VMX has to offer, all from a screen at home or in the office.

Visit [navc.com/vmx](http://navc.com/vmx) today to register for VMX 2021. Whether you decide to attend live and in person at the GBAC STAR-accredited Orange County Convention Center in Orlando, Florida or virtually, we hope you'll join us in our journey forward at VMX 2021, January 16-20. **TVP**



(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*).

#### DOSAGE 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.

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. Screw the applicator nozzle onto the dropperette.
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.

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 ingestion by humans, contact a physician immediately. In case of accidental skin contact, wash area thoroughly with water. Avoid contact with eyes. Humans with known hypersensitivity to florfenicol, terbinafine hydrochloride, or mometasone furoate should not handle this product.

#### PRECAUTIONS:

Do not administer orally.

The use of CLARO® in dogs with perforated tympanic membranes has not been evaluated. The integrity of the tympanic membrane should be confirmed before administering the product. 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=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, 2X, 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.

Manufactured for  
Bayer HealthCare LLC, Animal Health Division  
P.O. Box 390 Shawnee Mission, Kansas 66201 USA.

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