Think Veraflox® (pradofloxacin) Oral Suspension for Cats is just another antibiotic?

Put it to the test

This next-gen antimicrobial treatment† features a surprising combination of efficacy, safety and ease-of-use.

BACTERICIDAL against Gram-negative, Gram-positive and anaerobic bacteria*1

SAFE in kittens as young as 12 weeks of age2

CONVENIENT once-daily, vanilla-flavored oral suspension available in 15- and 30-mL bottles

Don’t believe it? Ask your lab to include Veraflox® on your next susceptibility tests.

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extra label use of this drug in food-producing animals. WARNING: For use in cats only. PRECAUTION: The safety of pradofloxacin in cats younger than 12 weeks of age has not been evaluated. 

*The clinical significance of in vitro data has not been demonstrated.

†Veraflox® is indicated for the treatment of skin infections (wounds and abscesses) in cats caused by susceptible strains of Pasteurella multocida, Streptococcus canis, Staphylococcus aureus, Staphylococcus felis, and Staphylococcus pseudintermedius.


2Freedom of Information Summary: NADA 141-344.

©2016 Bayer, Shawnee Mission, Kansas 66201. Bayer, the Bayer Cross and Veraflox are registered trademarks of Bayer. V161392
**INDICATION**

VERAFLOX is indicated for the treatment of skin infections (wounds and abscesses) in cats caused by susceptible strains of *Pseudomonas multocida*, *Staphylococcus aureus*, *Staphylococcus canis*, and *Staphylococcus pseudintermedius*.

**DOSE AND ADMINISTRATION**

Shake well before use. To ensure a correct dosage, body weight should be determined as accurately as possible. The dose of VERAFLOX is 7.5 mg (3.4 mg/lb) body weight once daily for 7 consecutive days. Use the syringe provided to ensure accuracy of dosing to the nearest 0.1 mL. Never syringe between doses. A sample of the lesion should be obtained for culture and susceptibility testing prior to beginning antibiotic therapy. Once results become available, continue with appropriate antibiotic therapy. If acceptable response to treatment is not observed, or if no improvement is seen within 5 to 7 days, then the diagnosis should be re-evaluated and appropriate alternative therapy considered.

**CONTRAINDICATIONS**

DO NOT USE IN DOGS. Pradofloxacin has been shown to cause bone marrow suppression in dogs. Dogs may be particularly sensitive to this effect, potentially resulting in severe thrombocytopenia and neutropenia.

Toxicity of bone marrow hematopoiesis should be avoided this product. Avoid contact with eyes and skin. In case of ocular contact, immediately flush eyes with copious amounts of water. In case of dermal contact, wash skin with soap and water immediately for at least 20 minutes. Consult a physician if irritation persists following ocular or dermal exposure, or in case of accidental ingestion. In humans, the pharmacokinetics of pradofloxacin within a few hours after exposure to quinolones. If excessive accidental exposure occurs, avoid direct sunlight. Do not eat, drink or smoke while handling this product. It is recommended that used syringes be kept out of reach of children and disposed of properly.

**WARNINGs**

For use in cats only. The administration of pradofloxacin for longer than 7 days induced reversible leukopeny, neutropenia, and lymphopenia decreases in healthy, 12-week-old kittens (see Animal Safety). If an unexplained adverse reaction or more than one occurrence of the same adverse reaction occurs during the study. The Material Safety Data Sheet (MSDS) provides additional occupational safety information. For customer use or to order product information, including a copy of the MSDS, contact Bayer HealthCare at 1-800-633-0796. For adverse reactions, contact Bayer HealthCare at 1-800-622-0774.

**CLINICAL PHARMACOLOGY**

**Pharmacokinetics:**

Pradofloxacin is rapidly absorbed following oral administration of VERAFLOX to fasted cats, with peak serum concentrations occurring in less than 1 hour. However, food markedly diminishes the serum bioavailability of pradofloxacin; mean peak serum concentrations (Cmax) are reduced 50% and mean exposures (AUC) are decreased by 26%. The relative bioavailability of pradofloxacin, when administered as the 2.5% oral suspension to fed and fasted cats, is provided in Table 2 and Figure 1.

**Pharmacodynamics:**

Pradofloxacin was determined using in vitro susceptibility that showed the pathogens *Pseudomonas multocida*, *Staphylococcus pseudintermedius*, and *Streptococcus spp.* had a pradofloxacin MIC of 0.005 to 0.12 mg/L. The pharmacokinetic parameters (AUC and CL) were estimated using linear regression analysis of free drug steady-state pradofloxacin pharmacokinetic parameters from ranges between 1.5 and 150 mg/kg. The study was designed so that the pradofloxacin concentration in plasma samples was determined by a validated HPLC method. In addition, effectiveness was shown for cats treated at 7.5 mg/kg body weight and fed free choice, or within two hours of dosing, in a field study.

**EFFECTIVENESS**

The overall effectiveness of VERAFLOX was demonstrated in a multi-site (16 sites) field study. In this masked and randomized study, the effectiveness of VERAFLOX was compared to a placebo control (vehicle with no active ingredient). Of the 282 cats enrolled in this study, 134 were treated with VERAFLOX once daily at 7.5 mg/kg (3.4 mg/lb) body weight for 7 consecutive days and 92 were treated with placebo once daily at 0.3 mL/kg body weight for 7 consecutive days. The effectiveness database included 136 treated cats and 116 VERAFLOX-treated cats. The analysis of this effectiveness database showed that the effectiveness rate was greater in the VERAFLOX group on Day 15, as summarized in Table 2 and Figure 1. Study cure rates were determined approximately 15 days after therapy began. The statistical evaluation of the primary effectiveness endpoint (Study Cure) showed that VERAFLOX was different from placebo at 73.4% VERAFLOX study cures versus 38.9% placebo study cures.

**TABLE 1: Number of Adverse Reactions Among Cats Treated with Pradofloxacin (N=190) or Vehicle (N=92)**

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Pradofloxacin</th>
<th>Vehicle</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diarrhea / loose stools</td>
<td>5</td>
<td>1</td>
<td>0.08</td>
</tr>
<tr>
<td>Leukocytosis with neutrophilia</td>
<td>3</td>
<td>1</td>
<td>0.54</td>
</tr>
<tr>
<td>Elevated CPK levels</td>
<td>3</td>
<td>2</td>
<td>0.54</td>
</tr>
<tr>
<td>Sneezing</td>
<td>3</td>
<td>1</td>
<td>0.20</td>
</tr>
<tr>
<td>Hematuria</td>
<td>2</td>
<td>0</td>
<td>0.47</td>
</tr>
<tr>
<td>Hypersalivation</td>
<td>4</td>
<td>1</td>
<td>0.01</td>
</tr>
<tr>
<td>Priapism</td>
<td>1</td>
<td>0</td>
<td>0.06</td>
</tr>
<tr>
<td>Impairment</td>
<td>2</td>
<td>0</td>
<td>0.20</td>
</tr>
<tr>
<td>Lethargy</td>
<td>1</td>
<td>1</td>
<td>0.54</td>
</tr>
<tr>
<td>Cardiac murmur</td>
<td>1</td>
<td>0</td>
<td>0.54</td>
</tr>
<tr>
<td>Reptile behavior</td>
<td>2</td>
<td>0</td>
<td>0.20</td>
</tr>
<tr>
<td>Vomiting</td>
<td>1</td>
<td>0</td>
<td>0.54</td>
</tr>
<tr>
<td>Bacteria</td>
<td>1</td>
<td>0</td>
<td>0.54</td>
</tr>
<tr>
<td>Lymphadenopathy</td>
<td>1</td>
<td>0</td>
<td>0.54</td>
</tr>
<tr>
<td>Polyuria</td>
<td>1</td>
<td>0</td>
<td>0.54</td>
</tr>
<tr>
<td>Upper respiratory infection</td>
<td>1</td>
<td>0</td>
<td>0.54</td>
</tr>
</tbody>
</table>

*Some cats may have experienced more than one adverse reaction or more than one occurrence of the same adverse reaction during the treatment.*

**TABLE 2: Mean (1 SD) Serum Pradofloxacin Derived Pharmacokinetic Parameters in Cats (N=12) Following a 5mg/kg Oral Dose of VERAFLOX under fasted and fed conditions.**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Fasted</th>
<th>Fed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cmax (mg/mL)</td>
<td>2116 (S49)</td>
<td>999 (40)</td>
</tr>
<tr>
<td>Tmax (hr)</td>
<td>0.4</td>
<td>0.5</td>
</tr>
<tr>
<td>AUC(0-24) (mg.L/24hr)</td>
<td>3118 (S49)</td>
<td>6748 (524)</td>
</tr>
<tr>
<td>AUC(0-inf) (mg.L/inf)</td>
<td>7.3</td>
<td>6.4</td>
</tr>
</tbody>
</table>

**Figure 1:** The effect of food on pradofloxacin bioavailability in cats.
Veraflex® (pradofloxacin) Oral Suspension for Cats

Veraflex® (pradofloxacin) Oral Suspension for Cats is the next step in veterinary antibiotic therapy for cats.

- Veraflex® is bactericidal, with activity against Gram-negative, Gram-positive and anaerobic bacteria.
- Veraflex® targeting of enzymes necessary for bacterial DNA replication.
- Extensive safety testing.
- Once-daily administration with a convenient, easy-to-deliver suspension.
- Easy-to-use dispenser makes accurate dosing simple.

Veraflex® is a registered trademark of Bayer.

An innovative antibiotic combining efficacy, safety and ease of use.

Veraflex® is approved for the treatment of skin infections (wounds and abscesses) in cats caused by susceptible strains of Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis and Staphylococcus pseudopseudomus.

Veraflex® was designed to improve upon the efficacy against Gram-positive and anaerobic pathogens versus previous generation fluorquinolones while delivering the same Gram-negative activity.

Veraflex® delivers enhanced bactericidal activity by attacking both of the essential target enzymes necessary for bacterial DNA replication – DNA gyrase and topoisomerase IV – with high affinity.

Efficacy

- The unique molecular structure of pradofloxacin was specifically engineered with high-affinity dual targeting to offer a broad-spectrum of bacterial activity compared to previous generation fluorquinolones.

Safety

- Veraflex® is labeled and approved for use in kittens and cats 12 weeks of age and older.
- The oral safety of Veraflex® was thoroughly tested using the most advanced methods.

Ease-of-use

- To help make Veraflex® convenient and easy to administer – which may help increase owner compliance – it comes in a flavor-free, well-aerated, once-daily oral suspension with a user-friendly, low-mess dispenser.

The clinical significance of in vitro data has not been demonstrated.


CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extra label use of this drug in food-producing animals. CONTRAINDICATIONS: Do not use in dogs. Pradofloxacin has been shown to cause bone marrow suppression in dogs. Pradofloxacin is contraindicated in cats with a known hypersensitivity to quinolones. WARNINGS: Notice for human use. Keep out of reach of children. Ensure in cats only. The administration of fluorquinolones for longer than 14 days induces reversible leukopenia, neutropenia, and lymphopenia decreases in healthy, 10-week-old kittens. PRECAUTIONS: The use of fluorquinolones in cats has been associated with retinopathy and blindness. Such products should be used with caution in cats. Refer to the product label for more complete list of risks and precautions.