

Date of Approval: March 3, 2006

FREEDOM OF INFORMATION SUMMARY

NADA 141-081

ORBAX Tablets

orbifloxacin

ORBAX Tablets (orbifloxacin) are indicated for the management of diseases in dogs and cats associated with bacteria susceptible to orbifloxacin.

Sponsored by:

Schering-Plough Animal Health Corp.
556 Morris Ave.
Summit, NJ 07901

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1. GENERAL INFORMATION:

- a. File Number: NADA 141-081
- b. Sponsor: Schering-Plough Animal Health Corp.
556 Morris Ave.
Summit, NJ 07901
- Drug Labeler Code: 000061
- c. Established Name: Orbifloxacin
- d. Proprietary Name: ORBAX Tablets
- e. Dosage Form: Tablet
- f. How Supplied: The product is available in the following presentations:
- 5.7 mg: yellow tablets in bottles of 250
- 22.7 mg: green single-scored (E-Z Break) tablets in bottles of 250
- 68 mg: blue single-scored (E-Z Break) tablets in bottles of 100
- g. How Dispensed: Rx
- h. Amount of Active Ingredients: Three tablet sizes: 5.7 mg, 22.7 mg, and 68 mg
- i. Route of Administration: Oral
- j. Species/Class: Canine and feline
- k. Recommended Dosage: 2.5 to 7.5 mg/kg of bodyweight administered once daily.
- For the treatment of skin and associated soft tissue infections, ORBAX Tablets should be given for two (2) to three (3) days beyond the cessation of clinical signs to a maximum of 30 days. For the treatment of urinary tract infections, ORBAX Tablets should be administered for at least ten (10) consecutive days.
- l. Pharmacological Category: Antimicrobial

- m. **Indications:** ORBAX Tablets (orbifloxacin) are indicated for the management of diseases in dogs and cats associated with bacteria susceptible to orbifloxacin.
- n. **Effect of Supplement:** The supplement adds post-approval adverse drug experience information and fluoroquinolone class statements regarding retinal toxicity in cats.

2. EFFECTIVENESS:

- a. Dosage Characterization:** New information was not required for this supplement.
- b. Substantial Evidence:** New information was not required for this supplement.

3. TARGET ANIMAL SAFETY:

Target Animal Safety was demonstrated for the original approval for the use of ORBAX Tablets in the dog approved on April 22, 1997 and for the supplemental approval for the use of ORBAX Tablets in the cat approved September 18, 1997.

The current changes to product labeling are based on post-approval drug experience report monitoring:

Warnings: Human warnings were changed to read “Warnings” and the following sentence was added under the Warnings section: “Do not exceed 7.5 mg/kg body weight per day in cats.”

Precautions: The following statements were added to the Precautions section: “The use of fluoroquinolones in cats has been reported to adversely affect the retina. Such products should be used with caution in cats.” The last statement in the Precautions section was changed from “Safety in breeding or pregnant dogs and cats has not been established” to read “The safety of orbifloxacin in animals that are used for breeding or that are pregnant and/or lactating has not been demonstrated.”

At the end of the Adverse Reactions section, a post-approval section was added. This section is entitled “Post Approval Experience” and contains the following language: “The following adverse reactions, although rare, are based upon voluntary post-approval reporting:

Hypersensitivity: facial edema, anaphylaxis/anaphylactoid reactions
Neurologic: seizures, ataxia
Behavioral: depression, lethargy
Gastrointestinal: vomiting, anorexia”

4. HUMAN SAFETY:

This drug is intended for use in dogs and cats, which are non-food animals. Because this new animal drug is not intended for use in food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this NADA.

Human Warnings are provided on the product label as follows: “**For use in animals only. Keep out of the reach of children.** Avoid contact with eyes. In case of contact, immediately flush eyes with copious amounts of water for 15 minutes. In case of dermal contact, wash skin with soap and water. Consult a physician if irritation persists following ocular or dermal exposure. Individuals with a history of hypersensitivity to quinolones should avoid this product. In humans, there is a risk of photosensitization within a few hours after excessive exposure to quinolones. If excessive accidental exposure occurs, avoid direct sunlight.”

5. AGENCY CONCLUSIONS:

The data submitted in support of this NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations. The data demonstrate that ORBAX Tablets when used under the labeled conditions of use is safe and effective. Clinical effectiveness was established in skin and soft tissue infections (wounds and abscesses) in the dog and cat and urinary tract infections (cystitis) in the dog.

The drug is restricted to use by or on the order of a licensed veterinarian because professional expertise is needed to diagnose and treat bacterial infections in dogs and cats.

This approval for ORBAX Tablets does not qualify for marketing exclusivity under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act.

According to the Center's supplemental approval policy (21 CFR 514.106), this is a Category II change. The approval of this change is not expected to have any adverse effect on the safety or effectiveness of this new animal drug.

Accordingly, this approval did not require a reevaluation of the safety and effectiveness data in the parent application.

6. ATTACHMENTS:

Facsimile labeling is attached as indicated below:

Package insert