

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in March 2022.

Original Approvals

This section displays the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

NADA Number: 141-551

Trade Name: Zenalpha®
Ingredients: Medetomidine and vatinoxan hydrochlorides
Sponsor: Vetcare Oy
Approval Date: March 30, 2022
Status: Rx
Route: Intramuscular
Species: Dog
Drug Form: Solution
Concentration: Each mL contains 0.5 mg medetomidine hydrochloride and 10 mg vatinoxan hydrochloride
Indications: For use as a sedative and analgesic in dogs to facilitate clinical examination, clinical procedures and minor surgical procedures.
Exclusivity: 5 years
Patent: Patent Number Expiration date:
 10058538 November 8, 2035
 9409919 December 14, 2035

ANADA Number: 200-720

Trade Name: Enroflox® Chewable Tablets
Pioneer: Baytril® Taste Tabs®
Ingredients: Enrofloxacin
Sponsor: Norbrook Laboratories, Ltd.
Approval Date: March 11, 2022
Status: Rx
Route: Oral
Species: Dogs and cats
Drug Form: Chewable tablet
Concentration: 22.7 mg, 68 mg, or 136 mg of enrofloxacin per tablet
Indications: For the management of diseases associated with bacteria susceptible to enrofloxacin.

ANADA Number: 200-722

Trade Name: Firox™
Pioneer: Previcox®
Ingredients: Firocoxib
Sponsor: Norbrook Laboratories, Ltd.
Approval Date: March 28, 2022
Status: Rx
Route: Oral
Species: Dogs
Drug Form: Chewable tablet
Concentration: 57 mg and 227 mg of firocoxib per tablet
Indications: For the control of pain and inflammation associated with osteoarthritis and for the control of postoperative pain and inflammation associated with soft-tissue and orthopedic surgery in dogs.

ANADA Number: 200-723

Trade Name: Tulieve®
Pioneer: Draxxin®
Ingredients: Tulathromycin
Sponsor: Norbrook Laboratories, Ltd.

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The following corrections or additions to the list were completed in March 2022.

Approval Date: March 23, 2022
Status: Rx
Route: Subcutaneous injection (cattle) and intramuscular injection (swine)
Species: Beef cattle, non-lactating dairy cattle, suckling calves, dairy calves, veal calves, and swine
Drug Form: Injectable solution
Concentration: 100 mg of tulathromycin/mL
Indications: **Beef and Non-Lactating Dairy Cattle:** For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis*; and for the control of respiratory disease in cattle at high risk of developing BRD associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis*.
For the treatment of infectious bovine keratoconjunctivitis associated with *Moraxella bovis*.
For the treatment of bovine foot rot (interdigital necrobacillosis) associated with *Fusobacterium necrophorum* and *Porphyromonas levii*.
Suckling Calves, Dairy Calves, and Veal Calves: For the treatment of BRD associated with *M. haemolytica*, *P. multocida*, *H. somni*, and *M. bovis*.
Swine: For the treatment of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Bordetella bronchiseptica*, *Haemophilus parasuis*, and *Mycoplasma hyopneumoniae*; and for the control of SRD associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, and *Mycoplasma hyopneumoniae* in groups of pigs where SRD has been diagnosed.

ANADA Number: 200-688

Trade Name: Tenotryl™
Pioneer: Baytril® 100
Ingredients: Enrofloxacin
Sponsor: Virbac AH, Inc.
Approval Date: March 28, 2022
Status: Rx
Route: Subcutaneous injection in beef and non-lactating dairy cattle
Intramuscular or subcutaneous (behind the ear) injection in swine
Species: Beef cattle, non-lactating dairy cattle, and swine
Drug Form: Injectable solution
Concentration: 100 mg/mL
Indications: **Cattle – Single-Dose Therapy:** For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni* and *Mycoplasma bovis* in beef and non-lactating dairy cattle; and for the control of BRD in beef and non-lactating dairy cattle at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, *H. somni* and *M. bovis*.
Cattle – Multiple-Day Therapy: For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida* and *Histophilus somni* in beef and non-lactating dairy cattle.
Swine: For the treatment and control of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Haemophilus parasuis*, *Streptococcus suis*, *Bordetella bronchiseptica* and *Mycoplasma hyopneumoniae*. It is also indicated for the control of colibacillosis in groups or pens of weaned pigs where colibacillosis associated with *Escherichia coli* has been diagnosed.

ANADA Number: 200-721

Trade Name: Midamox™ for Cats
Pioneer: advantage multi™ for cats
Ingredients: Imidacloprid and moxidectin
Sponsor: Norbrook Laboratories, Ltd.
Approval Date: March 28, 2022
Status: Rx
Route: Topical
Species: Cats

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Drug Form: Topical solution
Concentration: 100 mg/mL (10%) imidacloprid and 10 mg/mL (1%) moxidectin
Indications: For the prevention of heartworm disease caused by *Dirofilaria immitis*; kills adult fleas (*Ctenocephalides felis*) and is indicated for the treatment of flea infestations. It is also indicated for the treatment and control of ear mite (*Otodectes cynotis*) infestations, intestinal roundworms (*Toxocara cati*), and hookworms (*Ancylostoma tubaeforme*).

Animal Drug Safety-Related Labeling Changes

NADA Number: 141-459

Proprietary Name: Bravecto Topical for Cats

Drug Product Established Name: fluralaner topical solution

Safety-related changes made to the labeling are underlined below:

Dosage and Administration:

A veterinarian or veterinary technician should demonstrate or instruct the pet owner regarding the appropriate technique for applying Bravecto topically to cats prior to first use.

Step 1: Immediately before use, open the pouch and remove the tube. Put on gloves. Hold the tube at the crimped end with the cap in an upright position (tip up). The cap should be rotated clockwise or counter clockwise one full turn. The cap is designed to stay on the tube for dosing and should not be removed. The tube is open and ready for application when a breaking of the seal is felt.

Greasy, oily, or wet appearance may occur at the application site in some cats.

Human Warnings:

Not for human use. Keep this and all drugs out of the reach of children.

Do not contact or allow children to contact the application site until 2 hours Post application.

Keep the product in the original packaging until use in order to prevent children from getting direct access to the product. Do not eat, drink, or smoke while handling the product. Avoid contact with skin and eyes. If contact with eyes occurs, then flush eyes slowly and gently with water.

If wearing contact lenses, eyes should be rinsed first, then remove contact lenses and Continue rinsing, then seek medical advice immediately. Wash hands and contacted skin thoroughly with soap and water immediately after use of the product. If the product accidentally contacts skin and a sticky residue persists after washing, rubbing alcohol (70% isopropyl alcohol) can be applied to the area to remove the residue.

The product is highly flammable. Keep away from heat, sparks, open flame or other sources of ignition.

Post Approval Experience (2020):

The following adverse events are based on post-approval adverse drug experience reporting for fluralaner. Not all adverse events are reported to FDA/CVM. It is not always possible to reliably estimate the adverse event frequency or establish a causal relationship to product exposure using these data.

The following adverse events reported in cats are listed in decreasing order of reporting frequency:

Application site alopecia, lethargy, hypersalivation, anorexia, vomiting, behavioral disorders (including hyperactivity, hiding, and vocalization), generalized pruritus, application site disorders

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(including lesion, pruritus, and erythema), ataxia, alopecia, diarrhea, and muscle tremor.