

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in February 2020.

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: 141-521

Trade Name: Simparica Trio™
Ingredients: Sarolaner, moxidectin, and pyrantel
Sponsor: Zoetis Inc.
Approval Date: February 27, 2020
Status: Rx
Route: Oral
Species: Dogs
Drug Form: Chewable Tablet
Concentration: Each chewable tablet contains:
3.0 mg sarolaner / 0.06 mg moxidectin / 12.5 mg pyrantel (as pamoate salt)
6.0 mg sarolaner / 0.12 mg moxidectin / 25.0 mg pyrantel (as pamoate salt)
12.0 mg sarolaner / 0.24 mg moxidectin / 50.0 mg pyrantel (as pamoate salt)
24.0 mg sarolaner / 0.48 mg moxidectin / 100 mg pyrantel (as pamoate salt)
48.0 mg sarolaner / 0.96 mg moxidectin / 200 mg pyrantel (as pamoate salt)
72.0 mg sarolaner / 1.44 mg moxidectin / 300 mg pyrantel (as pamoate salt)
Indications: Simparica Trio™ prevents heartworm disease caused by *Dirofilaria immitis*, kills adult fleas (*Ctenocephalides felis*) and is indicated for the treatment and prevention of flea infestations, the treatment and control of tick infestations with *Amblyomma americanum* (lone star tick), *Amblyomma maculatum* (Gulf Coast tick), *Dermacentor variabilis* (American dog tick), *Ixodes scapularis* (black-legged tick), and *Rhipicephalus sanguineus* (brown dog tick), and the treatment and control of roundworm (immature adult and adult *Toxocara canis* and adult *Toxascaris leonina*) and adult hookworm (*Ancylostoma caninum* and *Uncinaria stenocephala*) infections for one month in dogs and puppies 8 weeks of age and older, and weighing 2.8 pounds or greater.
Exclusivity: 3 years
Patent: Patent Number Expiration date:
8466115 March 8, 2032
9226928 March 8, 2032
9200003 August 28, 2033

ANADA Number: 200-614

Trade Name: Pentobarbital Sodium and Phenytoin Sodium
Pioneer: BEUTHANASIA®-D SPECIAL
Ingredients: Pentobarbital sodium and phenytoin sodium
Sponsor: Akorn Animal Health, Inc.
Approval Date: February 7, 2020
Status: Rx
Route: Intravenous injection is preferred. Intracardiac injection may be made when intravenous injection is impractical, as in a very small dog or in a comatose dog with impaired vascular functions.
Species: Dogs
Drug Form: Injectable solution
Concentration: 390 mg/mL pentobarbital sodium and 50 mg/mL phenytoin sodium
Indications: For use in dogs for humane, painless, and rapid euthanasia.