**Packing Information**

**1. Product Information**

**1.1. Indications**

SIMPARICA is a flavored, chewable tablet for administration to dogs over 6 months of age according to their weight. Each tablet is formulated to provide a single dose of sarolaner. It is indicated for the prevention and treatment of flea and tick infestations in dogs, for the prevention of heartworm disease in dogs when used concurrently with a heartworm preventative (ivermectin/pyrantel pamoate), and for the prevention of gastrointestinal nematode infections in dogs when used concurrently with a broad-spectrum dewormer (ivermectin/piperazine/pyrantel pamoate).

**1.2. Usage**

Adverse Events:

The following adverse events are based on post-approval adverse drug experience reporting for SIMPARICA. 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.

**2. Mode of Action**

Sarolaner is a member of the isoxazoline class of parasiticides and the chemical name is 1-(5’-((5S)-5-(3,5-Dichloro-4-fluorophenyl)-5-(trifluoromethyl)-4,5-dihydroisoxazol-3-yl)ethan-1-yl)pyrrolidine. It is a nervous system depolarizer that inhibits voltage-gated sodium channels in the nervous system of insects, leading to depolarization of neurons and causing a rapid and sustained reduction in excitability.

**3. Administration**

- **Route of Administration**
  - Dogs: Chewable tablet
  - Cats: Not recommended for use in cats.
- **Dose and Administration**
  - Dogs: 1 tablet monthly for prevention and treatment of flea infestations, and for the prevention of heartworm disease and gastrointestinal nematode infections when used concurrently with a heartworm preventative and broad-spectrum dewormer, respectively.
  - Dosage is not recommended in dogs weighing less than 4.5 pounds.
- **Dosage Forms**
  - Tablets

**4. Animal Use**

- **Species**
  - Dogs
- **Weight**
  - Low end: 4.5 pounds
  - High end: 132.1 pounds
- **Dose**
  - 4.5 to 14.9 pounds: 1 tablet
  - 15.0 to 22.0 pounds: 2 tablets
  - 22.1 to 44.1 pounds: 3 tablets
  - 44.2 to 88.0 pounds: 4 tablets
  - 88.1 to 132.0 pounds: 5 tablets

**5. How Supplied**

- **Packaging**
  - Tablets
  - Tablets are formulated to provide sarolaner at different concentrations.
  - 4.5 to 14.9 pounds: 1 tablet
  - 15.0 to 22.0 pounds: 2 tablets
  - 22.1 to 44.1 pounds: 3 tablets
  - 44.2 to 88.0 pounds: 4 tablets
  - 88.1 to 132.0 pounds: 5 tablets

**6. Warnings**

- **Anaphylaxis**
  - SIMPARICA has been evaluated in dogs for anaphylaxis. There were no anaphylactic reactions reported in dogs treated with SIMPARICA.
- **Drug Interactions**
  - SIMPARICA is not recommended for use in dogs concurrently treated with other systemic antiparasitic agents, especially those that are neurotoxic.
- **Allergic Reactions**
  - SIMPARICA has been evaluated for allergic reactions in dogs. There were no allergic reactions reported in dogs treated with SIMPARICA.

**7. Adverse Reactions**

- **Dog Adverse Reactions**
  - 200104-02: 3/7/19
  - 200104-03: 3/7/19

**8. Additional Information**

- **FDA.gov**
  - www.fda.gov/reportanimalae.
- **For a copy of the Safety Data Sheet (SDS)**
  - or to report adverse reactions call Zoetis Inc. at 1-888-963-8471.
- **Additional information**
  - can be found at the following website: www.fda.gov/reportanimalae.

**9. References**

- **Post Approval Experience (2019):**
  - SIMPARICA was administered in a well-controlled US field study, which included a total of 479 dogs (315 dogs treated with SIMPARICA and 164 dogs treated with a concurrent heartworm preventative and broad-spectrum dewormer).
  - In this study, SIMPARICA demonstrated 99.9% flea control efficacy against susceptible fleas for 42 days post initial treatment.
  - SIMPARICA began to kill fleas 3 hours after initial administration and reduced the number of live fleas by 99.9% 48 hours post administration.
  - In well-controlled laboratory studies, SIMPARICA demonstrated >96% effectiveness against fleas at 28 days post initial treatment.

**10. Storage Information**

- **Stability**
  - SIMPARICA tablets are stable under usual room temperature storage conditions.
  - Keep SIMPARICA in a secure location out of reach of dogs, cats and other animals to prevent accidental ingestion or overdose.

**11. Federal (USA) Law**

- **Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.**