Post Approval Experience (2019).

Abnormal neurologic signs such as tremors, decreased conscious proprioception, ataxia, decreased or absent menace, and/or seizures were reported in dogs. One female dog aged 8.6 years exhibited lethargy, ataxia while posturing to eliminate, elevated third eyelids, and inappetence one day after receiving SIMPARICA. No seizures were reported in the control group.

Additionally, one female dog had seizures associated with the second dose and tremors associated with the fourth dose. Other similar reactions were observed in the 5X group, including seizures on Day 61 (5 days after third dose), tremors post-dose on Day 0, and abnormal neurologic signs on Day 1. In the 3X group, one female dog had a seizure on Day 61 (5 days after third dose), and another female dog had abnormal neurologic signs on Day 140.

Sarolaner is rapidly and well absorbed following oral administration of SIMPARICA. In a study of 12 Beagle dogs, the mean maximum plasma concentration (Cmax) ≥ 4 mg/kg after administration of SIMPARICA once every 28 days for 10 doses (8 dogs per group). The control group received placebo tablets. No neurologic signs were observed in the 1X group. In the 5X group, one female dog had a seizure on Day 61 (5 days after third dose); one female dog had tremors post-dose on Day 0 and abnormal neurologic signs on Day 140; and one female dog exhibited seizures associated with the second and fourth doses and tremors associated with the fifth dose.

Following repeat administration of SIMPARICA once every 28 days for 10 doses to Beagle dogs at 1X, 3X, and 5X the maximum intended clinical dose of 4 mg/kg, ≥ 99% effectiveness against an initial infestation of ≥ 2.8 pounds or greater of adult fleas. SIMPARICA demonstrated 100% effectiveness against adult fleas within 24 hours following treatment and maintained 100% effectiveness against adult fleas through Day 35. In a separate laboratory study, SIMPARICA demonstrated 100% effectiveness against adult flea infestations for 35 days.

In a study to explore flea egg production and viability, SIMPARICA killed fleas before they could lay eggs for 35 days. In a study to simulate a flea-infested home, SIMPARICA demonstrated 100% effectiveness against weekly re-infestations for 35 days. In a separate well-controlled laboratory study, SIMPARICA demonstrated 100% effectiveness against adult fleas within 24 hours following treatment and maintained ≥ 95.6% reduction in adult fleas within 14 days after treatment and reached 100% on Day 60.

Flea Treatment and Prevention:

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 minimum of 2 mg/kg of sarolaner. SIMPARICA contains the S-enantiomer of sarolaner.

SIMPARICA is given orally once a month at the recommended minimum dosage of 0.91 mg/lb (2 mg/kg).

Dosage Schedule:

SIMPARICA is given orally once a month at the recommended minimum dosage of 0.91 mg/lb (2 mg/kg).

Dosage and Administration:

DOSAGE SCHEDULE:

SIMPARICA Chewables are available in six flavored tablet sizes: 5, 10, 20, 40, 80, and 120 mg. Each tablet size is available in color-coded packages of one, three, or six tablets.

SIMPARICA is given orally once a month at the recommended minimum dosage of 0.91 mg/lb (2 mg/kg).

Storage:

Store at or below 30°C (86°F) with excursions permitted up to 40°C (104°F).

Revised: November 2020

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