This leaflet was formatted according to Ministry of Health guidelines.
This leaflet was reviewed and approved by the Ministry of Health in December 2018

Veterinary medicine package leaflet
This medicine is dispensed with a veterinary prescription only
For use in animals only

1. Name, form, and strength of the veterinary medicine

Simparica 10 mg Veterinary chewable tablets
Simparica 20 mg Veterinary chewable tablets
Simparica 40 mg Veterinary chewable tablets
Simparica 80 mg Veterinary chewable tablets
Simparica 120 mg Veterinary chewable tablets

2. Active substances

Each chewable tablet contains:

Simparica veterinary chewable tablets	**sarolaner (mg)**
for dogs >2.5-5 kg	10
for dogs >5-10 kg	20
for dogs >10-20 kg	40
for dogs >20-40 kg	80
for dogs >40-60 kg	120

For a list of the excipients see section 13: 'Additional information'.

3. What is the medicine intended for?

Indicated for dogs.
For the treatment of tick infestations (*Dermacentor reticulatus, Ixodes hexagonus, Ixodes ricinus,* and *Rhipicephalus sanguineus*). The veterinary medicine has immediate and persistent tick killing activity for at least 5 weeks.

For the treatment of flea infestations (*Ctenocephalides felis* and *Ctenocephalides canis*). The veterinary medicinal product has immediate and persistent flea killing activity against new infestations for at least 5 weeks.

The veterinary medicinal product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD).

For the treatment of sarcoptic mange (*Sarcoptes scabiei*).

For the treatment of ear mite infestations (*Otodectes cynotis*).

For the treatment of demodicosis (*Demodex canis*).

Fleas and ticks must attach to the host and commence feeding in order to be exposed to the active substance.

Therapeutic group: Ectoparasiticides for systemic use.

4. Contraindications

Do not use this medicine in case of known hypersensitivity to the active substance or to any of the excipients in this medicine (listed in section 13 'Additional information').

5. Adverse reactions

In very rare cases (fewer than 1 animal in 10,000, including isolated reports) adverse reactions associated with mild and transient gastrointestinal effects such as vomiting and diarrhea may occur. In very rare cases transient neurological disorders such as tremor, ataxia (inability to coordinate volitional movements) or convulsion may occur. These signs typically resolve without treatment.

If you notice any serious side effect, or any effect not listed in this package leaflet or you think that the medicine has not worked, please inform your veterinarian.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Medication' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:
https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

6. Target species

Dogs

7. Route of administration and dosage

For oral use.

This veterinary medicine should be administered at a dose of 2-4 mg/kg bodyweight in accordance with the following table:

Bodyweight (kg)	**Tablet strength (mg sarolaner)**	**Number of tablets to be administered**
>2.5–5	10	One
>5–10	20	One
>10–20	40	One
>20–40	80	One
>40–60	120	One
>60	Appropriate combination of tablets	

Use an appropriate combination of available strengths to achieve the recommended dose of 2-4 mg/kg bodyweight. The tablets should not be divided.

Tablets can be administered with or without food.

Treatment schedule:

For optimal control of flea and tick infestations, the veterinary medicine should be administered at monthly intervals and continue throughout the flea and tick season.

For the treatment of ear mite infestations (*Otodectes cynotis*) a single dose should be administered. A further veterinary examination 30 days after treatment is recommended as some animals may require a second treatment.

For the treatment of sarcoptic mange (caused by *Sarcoptes scabiei* var. *canis*) a single dose should be administered at monthly intervals for two consecutive months.

For the treatment of demodicosis (caused by *Demodex canis*) the administration of a single dose once monthly for three consecutive months is efficacious and leads to a marked improvement of clinical signs. Treatment should be continued until skin scrapings are negative on two consecutive occasions one month apart. As demodicosis is a multi-factorial disease, it is advisable to also treat any underlying disease.

8. Directions for use

Simparica tablets are chewable and palatable and readily consumed by dogs when offered by the owner. If the tablet is not taken up voluntarily by the dog it can also be given with food or directly into the mouth.

9. Withdrawal period

Not applicable.

10. Warnings

Special warnings about using this medicine in the target species
Parasites need to start feeding on the host to become exposed to sarolaner; therefore, the transmission of infectious parasite-borne diseases cannot be excluded.

Special warnings about the safety of using this medicine in animals
Puppies less than 8 weeks of age and/or dogs weighing less than 2.5 kg should not be treated unless the treatment is advised by a veterinarian.

Special warnings about the safety of the person administering this medicine
Wash hands after handling the product.

The accidental ingestion of the product may potentially result in side effects, such as transient excitatory neurological signs.

To prevent children from accessing the medicine, only one chewable tablet at a time should be removed from the blister pack and only when required. The blister pack should be returned into the carton immediately after use and the carton should be stored out of the reach and sight of children. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or package to the physician.

Pregnancy and lactation in the treated animal
The safety of the veterinary medicine has not been established during pregnancy and lactation or in animals intended for breeding. Laboratory studies in rats and rabbits have not produced any evidence of any teratogenic effects. Use only according to a benefit/risk assessment by the responsible veterinarian.

Interactions with other medicines and other forms of interactions
None known.

During clinical field trials, no interactions between Simparica veterinary chewable tablets for dogs and routinely used veterinary medicines were observed.

In laboratory safety studies, no interactions were observed when sarolaner was co-administered with milbemycin oxime, moxidectin and pyrantel pamoate. (In these studies efficacy was not investigated).

Sarolaner is highly bound to plasma proteins and might compete with other highly bound medicines such as non-steroidal anti-inflammatory drugs (NSAIDs) and the cumarin derivative warfarin (coumadin).

Overdose
In a margin of safety study, the medicine was administered orally to 8 week old Beagle puppies at doses of 0, 1, 3, and 5 times the maximum exposure dose of 4 mg/kg at 28 day intervals for 10 doses. No adverse effects were observed at the maximum exposure dose of 4 mg/kg. In the overdose groups, transient neurological signs were observed in some animals, for example: mild tremors at 3 times the maximum exposure dose and convulsions at 5 times the maximum exposure dose. All dogs recovered without treatment.

Sarolaner is well tolerated in Collies deficient in multidrug-resistance-protein 1 (MDR1 -/-) following single oral administration at 5 times the recommended dose. No treatment-related clinical signs were observed.

11. Storage instructions

- To prevent poisoning, keep this, and all other medicines, in a closed place out of the reach of children and/or infants. Prevent poisoning! Keep out of children's reach and sight.
- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- Storage conditions: Store below 30^{0}C.

12. Instructions for the disposal of unused medicine or remaining waste materials

Ask your veterinarian how to dispose of medicines no longer required. These measures will help protect the environment.

13. Additional information

- In addition to the active substance, this medicine also contains:
  Wheat germ
  Spray dried pork liver powder
  Hydoxypropyl methyl cellulose acetate succinate
  Corn syrup (81.5% solids)
  Sodium starch glycolate
  Calcium phosphate dibasic anhydrous
  Lactose monohydrate
  Confectioner's sugar
  Gelatin type A
  Colloidal silicon dioxide
  Magnesium stearate
  Corn starch
  Hydrolysed vegetable protein
- What the medicine looks like and contents of the package
  Mottled brown colored, square shaped chewable tablets with rounded edges. The number embossed on one side refers to the strength (mg) of the tablet: 10, 20, 40, 80, 120.
  For each strength, the chewable tablets are available in the following pack sizes: carton with one blister tray of 1, 3 and 6 tablets. Not all pack sizes may be marketed.

Registration Holder: Zoetis Israel Holding B.V, 5 Atir Yeda St., Kfar Saba

Manufacturer: Zoetis LLC (Subsidiary of Zoetis Inc.), 601 West Cornhusker Highway, Lincoln, NE 68521-3596, USA

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Registration number of the medicine in the Ministry of Health National Drug Registry:
Simparica 10 mg Veterinary: 161-30-35031-00/01
Simparica 20 mg Veterinary: 161-31-35032-00/01
Simparica 40 mg Veterinary: 161-32-35033-00/01
Simparica 80 mg Veterinary: 161-33-35034-00/01
Simparica 120 mg Veterinary: 161-34-35035-00/01

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