SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Simparica 120 mg chewable tablets for dogs >40–60 kg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:

Simparica chewable tablets	sarolaner (mg)
for dogs >40–60 kg	120

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Chewable tablets.
Mottled brown coloured, square shaped chewable tablets with rounded edges.

The number embossed on one side refers to the strength (mg) of the tablets: “120”.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

For the treatment of tick infestations (*Dermacentor reticulatus, Ixodes hexagonus, Ixodes ricinus* and *Rhipicephalus sanguineus*). The veterinary medicinal product 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*).

For reduction of the risk of infection with *Babesia canis canis* via transmission by *Dermacentor reticulatus* for 28 days after treatment. The effect is indirect due to the activity of the veterinary medicinal product against the vector.

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

4.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species

Transmission of *B. canis canis* cannot be completely excluded since *D. reticulatus* ticks have to attach to the host before being killed. As an acaricidal effect against *D. reticulatus* may take up to 48 hours, transmission of *B. canis canis* during the first 48 hours cannot be excluded.

The use of the veterinary medicinal product should be based on the local epidemiological situation including knowledge of the prevalent tick species as transmission of *B. canis* by tick species other than *D. reticulatus* is possible and should be part of an integrated control program to prevent the transmission of *Babesia canis*.

4.5 Special precautions for use

Special precautions for use in animals

In the absence of available data, treatment of puppies less than 8 weeks of age and/or dogs less than 1.3 kg bodyweight should be based on a benefit-risk assessment by the responsible veterinarian.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Wash hands after handling the veterinary medicinal product.

The accidental ingestion of the veterinary medicinal product may potentially result in adverse effects, such as transient excitatory neurological signs. To prevent children from accessing the veterinary medicinal product, only one chewable tablet at a time should be removed from the blister pack and only when required. The blister pack should then be returned into the carton immediately after use and the carton should be stored out of the sight and reach of children. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment
Not applicable.

Other precautions

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	gastrointestinal signs (such as vomiting, diarrhoea)[1] systemic disorders (such as lethargy, anorexia)[1] neurological signs (such as tremor, ataxia, convulsions)[2]

[1]Mild and transient.
[2]In most cases these signs are transient.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product 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.

Pregnancy and lactation:
The use in these animals is not recommended.

Fertility:
The use in breeding animals is not recommended.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

During clinical field trials, no interactions between this veterinary medicinal product and routinely used veterinary medicinal products 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 drugs such as non-steroidal anti-inflammatory drugs (NSAIDs) and the cumarin derivative warfarin.

4.9 Amount(s) to be administered and administration route

For oral use.
Tablets can be administered with or without food.

The veterinary medicinal product 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
>40–60	120	One
>60	Appropriate combination of tablets	

Use appropriate combination of available strengths to achieve the recommended dose of 2–4 mg/kg.

To ensure a correct dosage, bodyweight should be determined as accurately as possible.

The tablets of this veterinary medicinal product 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. The tablets should not be divided.

Treatment schedule:
For optimal control of tick and flea infestations, the veterinary medicinal product should be administered at monthly intervals and continue throughout the flea and/or tick season based on local epidemiological situations.

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 at least two consecutive occasions one month apart. As demodicosis is a multi-factorial disease, it is advisable to also treat any underlying disease appropriately.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

In a margin of safety study, the veterinary medicinal product 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 and self-limiting neurological signs were observed in some animals: 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 with a deficient multidrug-resistance-protein 1 (MDR1 -/-) following single oral administration at 5 times the recommended dose. No treatment-related clinical signs were observed.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for systemic use.

ATCvet code: QP53BE03.

5.1 Pharmacodynamic properties

Sarolaner is an acaricide and insecticide belonging to the isoxazoline family. The primary target of action of sarolaner in insects and acarines is functional blockade of ligand-gated chloride channels (GABA-receptors and glutamate-receptors). Sarolaner blocks GABA- and glutamate-gated chloride channels in the central nervous system of insects and acarines. Disruption of these receptors by sarolaner prevents the uptake of chloride ions by GABA and glutamate gated ion channels, thus resulting in increased nerve stimulation and death of the target parasite. Sarolaner exhibits higher functional potency to block insect/acarine receptors compared to mammalian receptors. Sarolaner does not interact with known insecticidal binding sites of nicotinic or other GABAergic insecticides such as neonicotinoids, fiproles, milbemycins, avermectins, and cyclodienes. Sarolaner is active against adult fleas (*Ctenocephalides felis* and *Ctenocephalides canis*) as well as several tick species such as *Dermacentor reticulatus, Ixodes hexagonus, Ixodes ricinus*, *Rhipicephalus sanguineus* and the mites *Demodex canis*, *Otodectes cynotis* and *Sarcoptes scabiei*.

For fleas, the onset of efficacy is within 8 hours of attachment during the 28 day period after the administration of the veterinary medicinal product. For ticks (*I. ricinus*), the onset of efficacy is within 12 hours of attachment during the 28 day period after the administration of the veterinary medicinal product. Ticks on the animal prior to administration are killed within 24 hours.

The veterinary medicinal product kills newly emerged fleas on the dog before they can lay eggs and therefore it prevents environmental flea contamination in areas to which the dog has access.

5.2 Pharmacokinetic particulars

The bioavailability of sarolaner following oral dosing was high at >85%. Sarolaner was dose proportional in Beagle dogs when dosed from the intended use dose of 2–4 mg/kg, to 20 mg/kg. The prandial state of the dog does not significantly affect the extent of its absorption.

Sarolaner was determined to have low clearance (0.12 ml/min/kg) and a moderate volume of distribution (2.81 l/kg). Half-life was comparable for the intravenous and oral routes at 12 and 11 days, respectively. Plasma protein binding was determined in vitro and calculated at ≥99.9%.

A distribution study determined that ^{14}C-sarolaner-related residues were widely distributed to the tissues. The depletion from tissues was consistent with the plasma half-life.

The primary route of elimination is biliary excretion of parent molecule, with elimination through the faeces.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hypromellose acetate succinate, medium grade
Lactose monohydrate
Sodium starch glycolate
Silica, colloidal anhydrous
Magnesium stearate
Maize starch
Confectioner's sugar
Glucose, liquid (81.5% solids)
Spray dried pork liver powder
Hydrolysed vegetable protein
Gelatin type A
Wheat germ
Calcium hydrogen phosphate anhydrous

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Aluminium foil/foil blister package.
One carton contains one blister of 1, 3 or 6 tablets.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

8. MARKETING AUTHORISATION NUMBER

Vm 42058/5049

9. DATE OF FIRST AUTHORISATION

06 November 2015

10. DATE OF REVISION OF THE TEXT

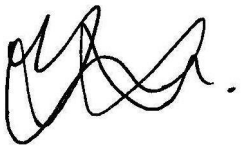
September 2023

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.



Approved: 22 February 2024