LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Simparica Trio chewable tablets for dogs >2.5–5 kg

sarolaner/moxidectin/pyrantel

2. STATEMENT OF ACTIVE SUBSTANCES

sarolaner 6 mg/moxidectin 0.12 mg/pyrantel (as embonate) 25 mg

3. PHARMACEUTICAL FORM

chewable tablet

4. PACKAGE SIZE

1 tablet
3 tablets
6 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Store below 30 °C.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/5055

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Simparica Trio >2.5–5 kg

6 mg/0.12 mg/25 mg

sarolaner/moxidectin/pyrantel

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Simparica Trio chewable tablets for dogs >2.5–5 kg

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

Manufacturer responsible for batch release:
Corden Pharma GmbH
Otto-Hahn-Str., Plankstadt
68723 Baden-Wuerttemberg
GERMANY

or

Zoetis Manufacturing & Research Spain, S.L.
Ctra. De Camprodón, s/n°
Finca La Riba
Vall de Bianya
Gerona 17813
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Simparica Trio chewable tablets for dogs >2.5–5 kg

Sarolaner, moxidectin, pyrantel (as embonate)

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each tablet contains:

Active substances:

Simparica Trio chewable tablets	sarolaner (mg)	moxidectin (mg)	pyrantel (as embonate) (mg)
for dogs 1.25–2.5 kg	3	0.06	12.5
for dogs >2.5–5 kg	6	0.12	25
for dogs >5–10 kg	12	0.24	50
for dogs >10–20 kg	24	0.48	100
for dogs >20–40 kg	48	0.96	200
for dogs >40–60 kg	72	1.44	300

Excipients:
Butylhydroxytoluene (E321, 0.018%). Colorants: Sunset Yellow FCF (E110), Allura Red (E129), Indigo Carmine (E132).

A reddish-brown colored, pentagon shaped tablet with rounded edges. Tablet is debossed with the sarolaner strength on one face of the tablet.

4. INDICATION(S)

For dogs with, or at risk from, mixed external and internal parasitic infestations. The veterinary medicinal product is exclusively indicated when use against ticks or fleas and gastrointestinal nematodes is indicated at the same time. The veterinary medicinal product also provides concurrent efficacy for the prevention of heartworm disease and angiostrongylosis.

Ectoparasites
- For the treatment of tick infestations. The veterinary medicinal product has immediate and persistent tick killing activity for 5 weeks against *Ixodes hexagonus, Ixodes ricinus* and *Rhipicephalus sanguineus* and for 4 weeks against *Dermacentor reticulatus*;
- 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 5 weeks;
- The veterinary medicinal product can be used as part of a treatment strategy for the control of flea allergy dermatitis (FAD).

Gastrointestinal nematodes
For the treatment of gastrointestinal roundworm and hookworm infections:
- *Toxocara canis* immature adults (L5) and adults;
- *Ancylostoma caninum* L4 larvae, immature adults (L5) and adults;
- *Toxascaris leonina* adults;
- *Uncinaria stenocephala* adults.

Other nematodes
- For the prevention of heartworm disease (*Dirofilaria immitis*);
- For the prevention of angiostrongylosis by reducing the level of infection with immature adult (L5) stages of *Angiostrongylus vasorum.*

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

Gastrointestinal signs such as vomiting and diarrhoea, and systemic disorders such as lethargy, anorexia/inappetence may occur in very rare cases based on post-marketing safety experience. In most cases these signs are mild and transient.

Neurological signs such as tremor, ataxia or convulsion may occur in very rare cases based on post-marketing safety experience. In most cases these signs are transient.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Oral use.

Dose
The veterinary medicinal product should be administered at a dose of 1.2–2.4 mg/kg of sarolaner, 0.024–0.048 mg/kg of moxidectin and 5–10 mg/kg of pyrantel in accordance with the following table:

Bodyweight (kg)	Tablet strength 3 mg/0.06 mg/12.5 mg	Tablet strength 6 mg/0.12 mg/25 mg	Tablet strength 12 mg/0.24 mg/50 mg	Tablet strength 24 mg/0.48 mg/100 mg	Tablet strength 48 mg/0.96 mg/200 mg	Tablet strength 72 mg/1.44 mg/300 mg
1.25–2.5 kg	1					
>2.5–5 kg		1				
>5–10 kg			1			
>10–20 kg				1		
>20–40 kg					1	
>40–60 kg						1
>60 kg	Appropriate combination of tablets					

Method of administration
Tablets can be administered with or without food.

Treatment schedule:
The treatment schedule should be based on veterinary diagnosis, the local epidemiological situation and/or the epidemiological situation of other areas the dog has visited or is going to visit. If based on veterinarian opinion re-administration(s) of the product is required, any subsequent administration(s) must follow the minimum 1-month interval schedule.

The product should only be used in dogs when treatment of ticks / fleas and gastrointestinal nematodes is indicated at the same time. In the absence of the risk of mixed co-infestation, a narrower spectrum parasiticide should be used.

Treatment of flea and tick infestations and gastrointestinal nematodes:
The veterinary medicinal product can be used as part of the seasonal treatment of fleas and ticks (replacing treatment with a mono-active flea and tick product) in dogs with diagnosed concurrent gastrointestinal nematode infections. A single treatment is efficacious for the treatment of gastrointestinal nematodes. After treatment of the nematode infections, further flea and tick treatment should be continued with a mono-active product.

Prevention of heartworm disease and angiostrongylosis:
A single administration also prevents lungworm disease (by reducing the immature adults (L5) of *A. vasorum*) and heartworm disease (*D. immitis*) for one month. When the product replaces another lungworm or heartworm preventive product, the first dose of the product should be given within a month of the last dose of the former veterinary medicinal product. In endemic areas, dogs should receive lungworm and/or heartworm preventive treatments at monthly intervals. It is recommended that heartworm prevention treatment should be continued until at least 1 month after the last exposure to mosquitoes.

9. ADVICE ON CORRECT ADMINISTRATION

Simparica Trio tablets are palatable and readily consumed by the majority of 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.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store below 30 °C.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and blister after EXP.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Ticks and fleas need to start feeding on the host to become exposed to sarolaner; therefore, the transmission of infectious parasite-borne diseases cannot be excluded.

This veterinary medicinal product is not effective against adult *D. immitis*. However, accidental administration to dogs infected with adult heartworms should not pose safety concerns. Dogs in areas endemic for heartworm (or those which have travelled to endemic areas) may be infected with adult heartworms. Maintenance of the efficacy of macrocyclic lactones is critical for *Dirofilaria immitis* control. To minimise the risk of resistance selection, it is recommended that dogs should be checked for both circulating antigens and blood microfilariae at the beginning of each season of preventative treatment. Only negative animals should be treated.

Parasite resistance to any particular class of parasiticides may develop following the frequent, repeated use of a product of that class. Therefore, the use of this product should be based on the assessment of each individual case and on local epidemiological information about the current susceptibility of the target species in order to limit the possibility of a future selection for resistance.

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 1.25 kg bodyweight should be based on a benefit-risk assessment by the responsible veterinarian.

The product was well tolerated in dogs with a deficient multidrug-resistance-protein 1 (MDR1 -/-). However, in such sensitive breeds (which may include, but not necessarily limited to, Collies and related breeds), the recommended dose should be strictly observed.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash hands after handling the product.

The accidental ingestion of the product may potentially result in adverse effects, such as transient excitatory neurological signs. To prevent children from accessing the 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 label to the physician.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation or in dogs intended for breeding. The use in these animals is not recommended.

Interaction with other medicinal products and other forms of interaction:
None known.

Macrocyclic lactones including moxidectin have been shown to be substrates for p-glycoprotein. Therefore, during treatment with the veterinary medicinal product, other

products that can inhibit p-glycoprotein (e.g. cyclosporine, ketoconazole, spinosad, verapamil) should only be used concomitantly according to the benefit-risk assessment of the responsible veterinarian.

Overdose (symptoms, emergency procedures, antidotes):
No adverse reactions were observed in 8-weeks old healthy puppies administered with up to 5 times the maximum recommended dose for 7 consecutive monthly administrations.

In a laboratory study, the product was well tolerated in dogs with a deficient multidrug-resistance-protein 1 (MDR1 -/-) following single oral administration at 3 times the recommended dose. After a single administration of 5 times the maximum recommended dose to this sensitive dog breed, transient ataxia and/or muscle fasciculation were observed.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

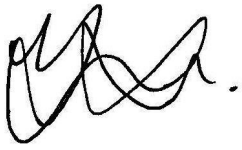
November 2022

15. OTHER INFORMATION

Ticks on the animal prior to administration or from new infestations after product administration are killed within 48 hours. For the species *I. Ricinus*, this onset of efficacy is within 24 hours, during the 35-day period after product administration.

For fleas, the onset of efficacy is within 12 to 24 hours of attachment for five weeks after product administration. Fleas on the animal prior to administration are killed within 8 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.

The tablets are packaged in aluminium foil/foil blisters packaged into an outer carton box.
Each tablet strength is available in pack sizes of 1, 3 or 6 tablets.
Not all pack sizes may be marketed.



Approved: 30 November 2022