PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CaniTrio chewable tablets for dogs 1.25–2.5 kg

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

sarolaner 3 mg/moxidectin 0.06 mg/pyrantel (as embonate) 12.5 mg

3. PACKAGE SIZE

1 tablet
3 tablets
6 tablets

4. TARGET SPECIES

Dogs.

5. INDICATION(S)

-

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

-

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Store below 30°C.
Keep the blister in the outer carton.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

14. MARKETING AUTHORISATION NUMBER

Vm 42058/5125

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

To be supplied only on veterinary prescription.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS {Blister}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CaniTrio

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

1.25–2.5 kg

3 mg/0.06 mg/12.5 mg

3. BATCH NUMBER

Lot

4. EXPIRY DATE

Exp. {mm/yyyy}

5. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CaniTrio chewable tablets for dogs 1.25–2.5 kg

2. COMPOSITION

Each tablet contains:

Active substances:

CaniTrio 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 coloured, pentagon shaped tablet with rounded edges. Tablet is debossed with the sarolaner strength on one face of the tablet.

3. TARGET SPECIES

Dogs

4. INDICATIONS FOR USE

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

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);
- For the treatment of sarcoptic mange (caused by *Sarcoptes scabiei* var. *canis*);
- For the treatment of demodicosis (caused by *Demodex canis*).

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.*
- For the treatment of *Angiostrongylus vasorum*;
- For the prevention of establishment of thelaziosis (adult *Thelazia callipaeda* eyeworm infection).

For reduction of the risk of infection with *Dipylidium caninum* via transmission by *Ctenocephalides felis* for one month after treatment. The effect is indirect due to product's activity against the vector.

5. CONTRAINDICATIONS

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

6. SPECIAL WARNING(S)

Special warnings:
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.

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic

species and burden, or of the risk of based on its epidemiological features, for each animal.

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.

The possibility that other animals in the same household can be a source of re-infection should be considered, and these should be treated as necessary with an appropriate product.

Special precautions for safe use in the target species:
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 the 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.

Fertility:
The safety of the veterinary medicinal product has not been established 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:
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.

7. ADVERSE EVENTS

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

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

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.

Underdosing could result in ineffective use and may favour resistance development.

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 / mites 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.

Treatment of angiostrongylosis (caused by Angiostrongylus vasorum):
A single dose should be administered. A further veterinary examination 30 days after treatment is recommended as some animals may require a second treatment.
A further assessment should then be carried out following the second treatment.
Continued monitoring should be performed as appropriate for each case.

Prevention of establishment of thelaziosis (adult Thelazia callipaeda eyeworm infection):
Monthly administration of the product prevents establishment of infection with adult *Thelazia callipaeda* eyeworm.

Treatment of demodicosis (caused by Demodex canis):
Administration of a single dose once monthly for two 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 multifactorial disease, it is advisable to also treat any contributing, underlying conditions appropriately.

Treatment of sarcoptic mange (caused by Sarcoptes scabiei var. canis):
Administration of a single dose at monthly intervals for two consecutive months.
Further monthly administrations of the product may be required based on clinical assessment and skin scrapings.

9. ADVICE ON CORRECT ADMINISTRATION

CaniTrio 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. The expiry date refers to the last day of that month.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

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.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

CaniTrio chewable tablets for dogs 1.25–2.5 kg	Vm 42058/5125
CaniTrio chewable tablets for dogs >2.5–5 kg	Vm 42058/5126
CaniTrio chewable tablets for dogs >5–10 kg	Vm 42058/5127
CaniTrio chewable tablets for dogs >10–20 kg	Vm 42058/5128
CaniTrio chewable tablets for dogs >20–40 kg	Vm 42058/5129
CaniTrio chewable tablets for dogs >40–60 kg	Vm 42058/5130

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

16. CONTACT DETAILS

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-Strasse 1
68723 Plankstadt
Germany

or

Zoetis Belgium S.A.
Rue Laid Burniat 1
Louvain-La-Neuve
1348
Belgium

17. 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.

Gavin Hall
Approved: 11 November 2025