Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
New Haw
Addlestone
Surrey KT15 3LS

NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

CaniTrio Chewable Tablets for Dogs 1.25–2.5 kg
CaniTrio Chewable Tablets for Dogs >2.5-5 kg
CaniTrio Chewable Tablets for Dogs >5-10 kg
CaniTrio Chewable Tablets for Dogs >10-20 kg
CaniTrio Chewable Tablets for Dogs >20-40 kg
CaniTrio Chewable Tablets for Dogs >40-60 kg

Date Created: February 2024

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	CaniTrio Chewable Tablets for Dogs 1.25–2.5 kg CaniTrio Chewable Tablets for Dogs >2.5-5 kg CaniTrio Chewable Tablets for Dogs >5-10 kg CaniTrio Chewable Tablets for Dogs >10-20 kg CaniTrio Chewable Tablets for Dogs >20-40 kg CaniTrio Chewable Tablets for Dogs >40-60 kg
Applicant	Zoetis UK Limited 1st Floor, Birchwood Building Springfield Drive Leatherhead Surrey KT22 7LP
Active substance	Sarolaner, moxidectin and pyrantel
ATC Vetcode	QP54AB52
Target species	Dogs
Indication 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 also provides concurrent efficacy for the prevention of heartworm disease, angiostrongylosis and thelaziosis. <u>Ectoparasites</u> – 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*). <u>Gastrointestinal nematodes</u> 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. <u>Other nematodes</u> – 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 prevention of establishment of thelaziosis (adult *Thelazia callipaeda* eyeworm infection).

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Product Information Database of the Veterinary Medicines Directorate.

(www.gov.uk/check-animal-medicine-licensed)

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Informed consent application in accordance with Article 13(c) of Directive 2001/82/EC as amended.
Date of conclusion of the procedure	17/01/2024

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of these products are identical to Simparica Trio Chewable Tablets for Dogs

V OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that the benefit/risk profile of the product(s) is favourable.

MODULE 4

POST- AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the Product Information Database of the Veterinary Medicines Directorate website.

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The post-authorisation assessment (PAA) contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

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