EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 July 2019
EMA/CVMP/364931/2019
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Simparica Trio

International non-proprietary name (INN): sarolaner / moxidectin / pyrantel embonate

On 18 July 2019, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Simparica Trio chewable tablets for dogs. The applicant for this veterinary medicinal product is Zoetis Belgium SA.

Simparica Trio is an antiparasitic medicinal product containing sarolaner / moxidectin / pyrantel embonate (ATCvet code QP54AB52) as active substances. Sarolaner is an acaricide and insecticide belonging to the isoxazoline family, moxidectin is a second generation macrocyclic lactone of the milbemycin family, whereas pyrantel is a nicotinic acetylcholine channel receptor agonist. In this fixed combination, sarolaner is active against fleas and ticks, while moxidectin and pyrantel provide complementary anthelmintic efficacy through distinct mechanisms of action.

The benefits of Simparica Trio are its efficacy in mixed external and internal parasitic infestations. The product is exclusively indicated when use against ticks or fleas and gastrointestinal nematodes is indicated at the same time; it also provides concurrent efficacy for the prevention of heartworm disease and angiostrongylosis.

Simparica Trio is generally well tolerated at the recommended dose; adverse reactions (transient ataxia and/or muscle fasciculation in dogs with a deficient multidrug-resistance-protein 1 (MDR1 -/-)) are only seen at overdoses.

The full indication is:

"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.

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued 67 days from adoption of the opinion.
[2] Applicants may appeal any CVMP opinion, provided they notify the European Medicines Agency in writing of their intention to appeal within 15 days of receipt of the opinion.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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.*"

Detailed conditions for the use of this product will be described in the summary of product characteristics (SPC) which will be published in the European public assessment report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit-risk balance for Simparica Trio and therefore recommends the granting of the marketing authorisation.