EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 February 2019
EMA/CVMP/112858/2019
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Felisecto Plus

International non-proprietary name (INN): selamectin / sarolaner

On 21 February 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 Felisecto Plus, spot-on solution, intended for use in cats. The applicant for this veterinary medicinal product is Zoetis Belgium SA.

Felisecto Plus is an antiparasitic medicinal product containing selamectin and sarolaner (ATCvet code QP54AA55) as active substances. Selamectin paralyzes and/or kills a wide range of invertebrate parasites through interference with their chloride channel conductance causing disruption of normal neurotransmission, whereas sarolaner blocks GABA- and glutamate-gated chloride channels in the central nervous system of insects and acarines, thus resulting in increased nerve stimulation and death of the target parasite.

The benefits of Felisecto Plus are its efficacy in the treatment and/or prevention of mixed external and internal parasitic infestations. The most common side effect is mild and transient pruritus at the application site; also, mild to moderate alopecia at the application site, erythema and drooling have been uncommonly observed.

The application for Felisecto Plus was an informed consent application. In an informed consent application, reference is made to an authorised medicine where the marketing authorisation holder of the reference medicine has given consent to the use of their dossier in the application procedure. The reference product for Felisecto Plus is Stronghold Plus (EU/2/16/204/001, 003, 005).

[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.

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The full indication is:

“For cats with, or at risk from, mixed parasitic infestations by ticks and fleas, lice, mites, gastrointestinal nematodes or heartworm. The veterinary medicinal product is exclusively indicated when use against ticks and one or more of the other target parasites is indicated at the same time.

Ectoparasites:

- For the treatment and prevention of flea infestations (*Ctenocephalides* spp.). The veterinary medicinal product has immediate and persistent flea killing activity against new infestations for 5 weeks. The product kills adult fleas before they lay eggs for 5 weeks. Through its ovicidal and larvicidal action, the veterinary medicinal product may aid in the control of existing environmental flea infestations in areas to which the animal has access.
- The product can be used as part of a treatment strategy for flea allergy dermatitis.
- Treatment of tick infestations. The veterinary medicinal product has immediate and persistent acaricidal effect for 5 weeks against *Ixodes ricinus* and *Ixodes hexagonus*, and 4 weeks against *Dermacentor reticulatus* and *Rhipicephalus sanguineus*.
- Treatment of ear mites (*Otodectes cynotis*).
- Treatment of biting lice infestations (*Felicola subrostratus*).

Ticks must attach to the host and commence feeding in order to be exposed to sarolaner.

Nematodes:

- Treatment of adult roundworms (*Toxocara cati*) and adult intestinal hookworms (*Ancylostoma tubaeforme*).
- Prevention of heartworm disease caused by *Dirofilaria immitis* with monthly administration.”

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 for the originator product Stronghold Plus and the informed consent accepted for this application, considers that there is a favourable benefit-risk balance for Felisecto Plus and therefore recommends the granting of the marketing authorisation.