9 December 2016
EMA/CVMP/707464/2016
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Stronghold Plus

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

On 8 December 2016, 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 Stronghold Plus, 15 mg/2.5 mg, 30 mg/5 mg, and 60 mg/10 mg selamectin/sarolaner, spot-on solutions, intended for cats with, or at risk from, mixed parasitic infestations. The applicant for this veterinary medicinal product is Zoetis Belgium SA.

Stronghold Plus is an antiparasitic medicinal product (ATCvet code QP54AA55). The active substances are selamectin and sarolaner.

Selamectin is an ectoparasiticide and anthelmintic which paralyses and/or kills a range of invertebrate parasites through interference and disruption of neurotransmission by inhibition in nematodes and muscle cells in arthropods leading to their paralysis and/or death.

Sarolaner is an acaricide and insecticide which works by increased nerve stimulation and death of the target parasites.

The benefits of Stronghold Plus are its efficacy in 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. The most common side effects are mild and transient pruritus at the application site. Mild to moderate alopecia at the application site, erythema and drooling have been uncommonly observed.

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.

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