16 January 2015
EMA/737305/2014
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Stronghold

International non-proprietary name (INN): Selamectin

On 15 January 2015, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted an opinion[2], recommending the granting of a grouped extension to the terms of the marketing authorisation for the veterinary medicinal product Stronghold. The marketing authorisation holder for this veterinary medicinal product is Zoetis Belgium SA.

Stronghold is currently authorised as a spot-on solution for dogs (strengths of 15 mg, 30 mg, 60 mg, 120 mg and 240 mg) and for cats (strengths of 15 mg and 45 mg).

This grouped extension application concerns the addition of a new spot-on strength of 360 mg for dogs and 60 mg for cats.

Detailed conditions for the use of this product are described in the summary of product characteristics (SPC) for which an updated version reflecting the changes 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 to risk balance for Stronghold and therefore recommends the granting of the extension of the marketing authorisation.

[1] Summaries of opinion are published without prejudice to the Commission Decision.
[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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