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EMA/138670/2019
Veterinary Medicines Division

Committee for Medicinal Products for Veterinary Use

CVMP assessment report for Felisecto Plus (EMEA/V/C/005093/0000)

International non-proprietary name: selamectin / sarolaner

Assessment report as adopted by the CVMP with all information of a commercially confidential nature deleted.

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Introduction

The applicant Zoetis Belgium SA submitted on 26 November 2018 an application for a marketing authorisation to the European Medicines Agency (The Agency) for Felisecto Plus through the centralised procedure in accordance with Regulation (EC) No 726/2004. The eligibility to the centralised procedure was agreed upon by the CVMP on 21 June 2018.

The legal basis for this application refers to Article 13c of Directive 2001/82/EC, relating to informed consent from a marketing authorisation holder for a centrally authorised veterinary medicinal product: Stronghold Plus (EU/2/16/204/001, 003 and 005).

This application is submitted as a multiple application of the centrally authorised product Stronghold Plus in accordance with Article 82(1) of Regulation (EC) No 726/2004.

The applicant applied for the following indications: 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 (FAD).
- 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.

The active substances of Felisecto Plus are selamectin and sarolaner. Selamectin is a semi-synthetic compound of the avermectin class. Selamectin paralyses and/or kills a wide range of invertebrate parasites through interference with their chloride channel conductance causing disruption of normal neurotransmission. This inhibits the electrical activity of nerve cells in nematodes and muscle cells in arthropods leading to their paralysis and/or death. Sarolaner is an acaricide and insecticide belonging to the isoxazoline family. The primary target of action of sarolaner in insects and acarines is functional blockade of ligand-gated chloride channels (GABA-receptors and glutamate-receptors). Sarolaner blocks GABA- and glutamate-gated chloride channels in the central nervous system of insects and acarines. Disruption of these receptors by sarolaner prevents the uptake of chloride ions by GABA and glutamate

gated ion channels, thus resulting in increased nerve stimulation and death of the target parasite. The target species is cats.

Felisecto Plus is a spot-on solution presented in single-dose pipettes containing 15 mg/2.5 mg, 30 mg/5 mg or 60 mg/10 mg of selamectin/sarolaner, respectively, and is available in packs containing 3 pipettes.

The rapporteur appointed is Rory Breathnach and the co-rapporteur is Cristina Muñoz Madero.

The dossier has been submitted in line with the requirements for submissions under Article 13c of Directive 2001/82/EC – an informed consent application from the marketing authorisation holder for Stronghold Plus for which consent has been given (EU/2/16/204/001, 003 and 005).

On 21 February 2019, the CVMP adopted an opinion and CVMP assessment report.

On 26 April 2019, the European Commission adopted a Commission Decision granting the marketing authorisation for Felisecto Plus.

Scientific advice

Not applicable.

MUMS/limited market status

Not applicable.

Part 1 - Administrative particulars

Detailed description of the pharmacovigilance system

The applicant has provided a detailed description of the pharmacovigilance system (dated 28 May 2018) which fulfils the requirements of Directive 2001/82/EC. Based on the information provided, the applicant has the services of a qualified person responsible for pharmacovigilance and the necessary means for the notification of any adverse reaction occurring either in the Union or in a third country.

Manufacturing authorisations and inspection status

Manufacture of the dosage form along with both primary and secondary packaging takes place outside the EEA. This site has a GMP certificate issued by the French competent authority, which confirms the date of the last inspection and shows that the site is authorised for the manufacture, primary and secondary packaging of such veterinary dosage forms.

Batch release within the EU takes place at Zoetis Belgium SA, Louvain-La-Neuve, Belgium. This site holds a GMP certificate issued by the Belgian competent authority, issued following an inspection. This site is also in receipt of a manufacturing authorisation.

A declaration has been provided from the QP of the batch release site that the active substance selamectin manufactured by both suppliers is in accordance with GMP requirements for starting materials. The QP declaration is made following on-site audits.

A separate QP declaration has been provided from the QP of the batch release site indicating that the active substance sarolaner is manufactured in accordance with GMP requirements for starting materials. The QP declaration is made following an on-site audit.

Overall conclusions on administrative particulars

The detailed description of the pharmacovigilance system was considered in line with legal requirements.

The GMP status of the finished product manufacturing site has been satisfactorily established and is in line with legal requirements.

Part 2 - Quality

This application is an informed consent of Stronghold Plus spot-on solution for cats.

The quality data in support of this application are identical to the up-to-date quality data of the dossier for Stronghold Plus spot-on solution for cats, which has already been assessed and approved by the CVMP (including any post-marketing procedures).

Therefore, no quality data have been submitted. This is considered acceptable given the legal basis of this application (informed consent).

Part 3 – Safety

This application is an informed consent of Stronghold Plus spot-on solution for cats.

The safety data in support of this application are identical to the up-to-date safety data of the dossier for Stronghold Plus spot-on solution for cats, which has already been assessed and approved by the CVMP (including any post-marketing procedures).

Therefore, no safety data have been submitted. This is considered acceptable given the legal basis of this application (informed consent).

To ensure comprehensive adverse event surveillance and to benefit from the possibility of aligning periodic safety update report (PSUR) submissions for informed consent products as foreseen in the legislation, PSUR submissions should be synchronised and common PSURs should be submitted for the informed consent product, Felisecto Plus, and the originator product, Stronghold Plus, which is currently on a six monthly cycle. The next data lock point (DLP) for a common PSUR is 31/08/2019 to cover period from 01/03/2019 to 31/08/2019.

In addition, surveillance of the data in EudraVigilance Veterinary (EVVet) will also be synchronised for signal detection of the two products.

Part 4 – Efficacy

This application is an informed consent of Stronghold Plus spot-on solution for cats.

The efficacy data in support of this application are identical to the up-to-date efficacy data of the dossier for Stronghold Plus spot-on solution for cats, which has already been assessed and approved by the CVMP (including any post-marketing procedures).

Therefore, no efficacy data have been submitted. This is considered acceptable given the legal basis of this application (informed consent).

Part 5 – Benefit-risk assessment

This marketing authorisation application for Felisecto Plus spot-on solution for cats has been submitted by Zoetis Belgium SA as an informed consent application in accordance with Article 13c of Directive 2001/82/EC.

As a consequence, the quality, safety and efficacy of Felisecto Plus are identical to the up-to-date quality, safety and efficacy profile of Stronghold Plus. The application for Felisecto Plus concerns the identical strengths to those approved for Stronghold Plus and consists of only Part 1. Information on the scientific discussion can be found in the European Public Assessment Report (EPAR) for Stronghold Plus published on the EMA website.

Consequentially, and in line with the assessment of data undertaken in the framework of the initial marketing authorisation application as well as within all post-authorisation procedures for Stronghold Plus spot-on solution for cats, the CVMP considers that the benefit-risk balance for Felisecto Plus is positive.

To ensure comprehensive adverse event surveillance, signal detection and PSUR submissions will be synchronised with those for Stronghold Plus.

Conclusion

Based on the original and complementary data presented on quality, safety and efficacy for the authorised originator product Stronghold Plus and the informed consent accepted for this application, the Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the application for Felisecto Plus is approvable since these data satisfy the requirements for an authorisation set out in the legislation (Regulation (EC) No 726/2004 in conjunction with Directive 2001/82/EC).

The CVMP considers that the benefit-risk balance is positive and, therefore, recommends the granting of the marketing authorisation for the above mentioned medicinal product.