10 September 2021
EMA/CVMP/494159/2021
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Felpreva

International non-proprietary name (INN): tigolaner / emodepside / praziquantel

On 9 September 2021, 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 Felpreva, spot-on solution, intended for cats. The applicant for this veterinary medicinal product is Vetoquinol SA.

Felpreva is a fixed combination of three antiparasitic active ingredients, containing tigolaner, an acaricide and insecticide belonging to the chemical class of bispyrazoles, emodepside, an antiparasitic belonging to the cyclic depsipeptide class and praziquantel, a pyrazino-isoquinoline (ATCvet code: QP52AA51). In combination these active substances are proposed to treat endoparasite infestations as well as treatment and control of ectoparasites. The target species is cats.

The benefits of Felpreva are that it has been shown to be effective against the mixed parasites infections indicated and increases the range of available treatment possibilities for concurrent ectoparasitic, cestodes and nematode infections in cats.

The most common side effects are mild and transient application site reactions. Felpreva is generally well tolerated at the recommended dose. The appropriate CVMP guidelines on data requirements for veterinary medicinal products intended for minor use or minor species/limited markets have been applied in the assessment of the application.

The full indication is:

"For cats with, or at risk from, mixed parasitic infestations/infections. The veterinary medicinal product is exclusively indicated when ectoparasites, cestodes and nematodes are targeted at the same time.

[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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Ectoparasites

- For the treatment of flea (*Ctenocephalides felis*) and tick (*Ixodes ricinus, Ixodes holocyclus*) infestations in cats providing immediate and persistent killing activity for 13 weeks.
- The veterinary medicinal product can be used as part of a treatment strategy for the control of flea allergy dermatitis (FAD).
- For the treatment of mild to moderate cases of notoedric mange (*Notoedres cati*).
- For the treatment of ear mite infestations (*Otodectes cynotis*)

Gastrointestinal roundworms (nematodes)

- For the treatment of infections with:
- *Toxocara cati* (mature adult, immature adult, L4 and L3)
- *Toxascaris leonina* (mature adult, immature adult and L4)
- *Ancylostoma tubaeforme* (mature adult, immature adult and L4)

Lungworms (nematodes)

- For the treatment of infections with:
- *Aelurostrongylus abstrusus* (adult)
- *Troglostrongylus brevior* (adult)

Tapeworms (cestodes)

- For the treatment of tapeworm infections:
- *Dipylidium caninum* (mature adult and immature adult)
- *Taenia taeniaeformis* (adult)"

Detailed conditions for the use of this product are 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 Felpreva and therefore recommends the granting of the marketing authorisation.