6 November 2020
EMA/CVMP/535061/2020
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

NexGard Combo

International non-proprietary names (INN): esafoxolaner / eprinomectin / praziquantel

On 5 November 2020, 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 NexGard Combo, Spot-on solution, intended for Cats. The applicant for this veterinary medicinal product is Boehringer Ingelheim Vetmedica GmbH.

NexGard Combo is an antiparasitic veterinary medicinal product containing a fixed combination of esafoxolaner / eprinomectin / praziquantel (ATCvet code QP54AA54) as active substances.

Esafoxolaner is the S-enantiomer of afoxolaner, an ectoparasiticide belonging to the isoxazoline group. It acts as an antagonist at ligand-gated chloride channels (GABA), thereby blocking pre-and post-synaptic transfer of chloride ions across cell membranes, resulting in uncontrolled activity of the central nervous system and death of ectoparasites. Eprinomectin is a member of the macrocyclic lactone class, and active against gastrointestinal and extraintestinal nematodes. It causes an increase in the permeability of cell membranes to chloride ions, resulting in paralysis and death of the nematodes. Praziquantel is a synthetic isoquinoline-pyrazine derivative with activity against tapeworms. It acts by damaging the parasite's integument resulting in paralysis and death of the cestodes.

The benefit of NexGard Combo is its efficacy in the treatment of cats with (or at risk from) mixed infections with ectoparasites and nematodes and cestodes. The product is also effective as part of a treatment strategy for the control of flea allergy dermatitis.

NexGard Combo is generally well tolerated by cats at the recommended dose; adverse reactions include uncommon and transient cases of hypersalivation, diarrhoea, anorexia, lethargy and emesis shortly after administration, and skin reactions at the application site. The veterinary medicinal product can cause eye irritation, and users are therefore advised to avoid contact of the applicator content with their fingers.

[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 infections by cestodes, nematodes and ectoparasites. The veterinary medicinal product is exclusively indicated when all three groups are targeted at the same time.

Ectoparasites

Treatment of infestations by fleas (*Ctenocephalides felis*). One treatment provides immediate and persistent flea killing activity for one month.

The product can be used as part of a treatment strategy for the control of flea allergy dermatitis.

Treatment of infestations by ticks. One treatment provides immediate and persistent tick killing activity against *Ixodes scapularis* for one month and against *Ixodes ricinus* for five weeks.

Treatment of infestations by ear mites (*Otodectes cynotis*).

Gastro-intestinal cestodes

Treatment of infections with tapeworms (*Dipylidium caninum, Taenia taeniaeformis, Echinococcus multilocularis, Joyeuxiella pasqualei and Joyeuxiella fuhrmanni*).

Nematodes

Gastro-intestinal nematodes:

Treatment of infections with gastrointestinal nematodes (L3, L4 larvae and adults of *Toxocara cati*, L4 larvae and adults of *Ancylostoma tubaeforme* and *Ancylostoma ceylanicum*, and adult forms of *Toxascaris leonina* and *Ancylostoma braziliense*).

Cardio-pulmonary nematodes:

Prevention of heartworm disease (*Dirofilaria immitis*) for one month.

Treatment of infections with feline lungworms (L4 larvae and adults of *Troglostrongylus brevior*).

Vesical nematodes:

Treatment of infections with vesical worms *(Capillaria plica)."*

Detailed conditions for the use of this product are described in the summary of product characteristics 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 NexGard Combo and therefore recommends the granting of the marketing authorisation.