11 October 2019
EMA/CVMP/515319/2019
Committee for Medicinal Products for Veterinary Use

**Summary of opinion[1] (initial authorisation)**

# Miratax

## International non-proprietary name (INN): mirtazapine

On 10 October 2019, 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 Miratax, a transdermal ointment, intended for cats. The applicant for this veterinary medicinal product is Aniserve GmbH. The applicant is registered as an SME pursuant to the definition set out in Commission Recommendation 2003/361/EC.

Miratax is an antidepressant veterinary medicinal product containing mirtazapine (ATCvet code QN06AX11) as active substance, which is a potent antagonist of 5-HT2 and 5-HT3 receptors in the central nervous system (CNS), and a potent inhibitor of histamine H1 receptors. Inhibition of 5-HT2 and histamine H1 receptors may account for the orexigenic effects of the molecule.

The benefit of Miratax is that it induces weight gain in cats with underlying chronic medical conditions. The most common side effects are application site reactions and behavioural changes.

The full indication is: for bodyweight gain in cats experiencing poor appetite and weight loss resulting from chronic medical conditions.

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.

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

[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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