European Medicines Agency
Veterinary Medicines and Inspections

London, 19 September 2008
Doc. Ref.: EMEA/CVMP/405937/2008

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE
SUMMARY OF OPINION*
EASOTIC

International Non-proprietary Name (INN):
Combined hydrocortisone aceponate, miconazole nitrate, gentamicin sulphate

On 17 September 2008, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the veterinary medicinal product Easotic ear drops suspension for dogs, intended for treatment of acute otitis externa, and acute exacerbation of recurrent otitis externa associated with bacteria susceptible to gentamicin and fungi susceptible to miconazole in particular *Malassezia pachydermatis*. The Applicant for this veterinary medicinal product is Virbac S.A.

The active substances of Easotic are combined hydrocortisone aceponate, miconazole nitrate and gentamicin sulphate. Easotic is an otologic medicinal product, ATCvet code: QS02CA03, containing in combination a corticosteroid, anti-fungal and an antibiotic.

The benefits of Easotic are it is an easy to apply ear suspension, administered once daily with an airless pump via a cannula to a dog in any position. Easotic has antibacterial, antifungal, and anti-inflammatory action and these combined actions are sought in the treatment of external ear infections. The combination shows a good success rate in the treatment of ear infection overall. The antibacterial components address the bacterial and fungal components of the disease whereas the anti-inflammatory component reduces the swelling of the ear and also provides pain relief. The most common side effects are mild to moderate redness of the ears.

The approved indication is: "treatment of acute otitis externa, and acute exacerbations of recurrent otitis externa associated with bacteria susceptible to gentamicin and fungi susceptible to miconazole in particular *Malassezia pachydermatis*".

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 to risk balance for Easotic and therefore recommends the granting of the marketing authorisation.

* Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the Opinion.

** Applicants may appeal any CVMP opinion, provided they notify the EMEA in writing of their intention to appeal within 15 days of receipt of the opinion.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 47
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

© European Medicines Agency, 2008. Reproduction is authorised provided the source is acknowledged.