European Medicines Agency
Veterinary Medicines and Inspections

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

International Non-proprietary Name (INN):
Orbifloxacin, Mometasone furoate and Posaconazole

On 16 April 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 Posatex, ear-drops suspension for dogs, intended for treatment of acute otitis externa and acute exacerbations of recurrent otitis externa, associated with bacteria susceptible to orbifloxacin and fungi susceptible to posaconazole, in particular *Malassezia pachydermatis.* The Applicant for this veterinary medicinal product is S-P Veterinary, United Kingdom.

The active substances of Posatex are orbifloxacin, mometasone furoate monohydrate and posaconazole. Posatex is an otologic medicinal product, ATC vet code: QS02CA91, containing in combination a corticosteroid, an antifungal and a broad spectrum fluoroquinolone antibiotic to treat otitis externa in dogs.

The benefits of Posatex, include that it is an easy to apply ear ointment, administered once daily, with antibacterial, antifungal, and anti-inflammatory action and these combined actions are sought in the treatment of external ear infections in the dog. 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 erythematous lesions.

The approved indication is: "Treatment of acute otitis externa and acute exacerbations of recurrent otitis externa, associated with bacteria susceptible to orbifloxacin and fungi susceptible to posaconazole, 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 Posatex and therefore recommends the granting of the marketing authorisation.

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* 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