9 February 2011
EMA/CVMP/411755/2010-Rev.1
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1]

Veraflox

pradofloxacin

On 9 February 2011, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a revised positive opinion,** recommending to grant a marketing authorisation for the veterinary medicinal product Veraflox 15 mg, 60 mg & 120 mg Tablets and 2.5% Oral Suspension. The revision was at the request of the Commission further to the Standing Committee procedure, and resulted in some amendment of the proposed Summary of Product Characteristics (SPC) and package leaflet.

Veraflox Tablets are intended for the treatment of dogs with the following infections caused by certain specified and susceptible pathogens: wound infections; superficial and deep pyoderma; acute urinary tract infections; and, as adjunctive treatment for severe infections of the gingival and periodontal tissues.

Veraflox Tablets are also intended for the treatment of cats with acute infections of the upper respiratory tract caused by certain specified and susceptible pathogens.

Veraflox 2.5% Oral Suspension is intended only for the treatment of cats with the following infections caused by certain specified and susceptible pathogens: acute infections of the upper respiratory tract; wounds and abscesses.

The applicant for this veterinary medicinal product is Bayer Animal Health GmbH.

The active substance of Veraflox is pradofloxacin, a third generation fluoroquinolone antibiotic (ATCvet code: QJ01MA). Pradofloxacin exerts its bactericidal effects by its interaction with enzymes responsible for major DNA functions.

The benefits of Veraflox are its enhanced spectrum of antimicrobial activity (including Gram positive and anaerobic bacteria) when compared to other fluoroquinolones. Adverse reactions in dogs and cats are limited to mild transient gastro-intestinal disturbances, including vomiting, and are observed only rarely.

[1] 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 EMA in writing of their intention to appeal within 15 days of receipt of the opinion.

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Veraflox can be harmful to children ingesting the product accidentally. Therefore Veraflox tablets and filled syringes of Veraflox oral suspension should be kept out of the reach and sight of children.

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 Veraflox and therefore recommends the granting of the marketing authorisation.