European Medicines Agency
Veterinary Medicines and Inspections

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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE
SUMMARY OF OPINION*

ONSIOR

International Non-proprietary Name (INN):
Robenacoxib

On 15 October 2008 the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending the granting of a marketing authorisation for the veterinary medicinal product Onsior, tablets and solution for injection for dogs and cats intended for the treatment of pain and inflammation. The Applicant for this veterinary medicinal product is Novartis Animal Health (UK) Ltd..

The active substance of Onsior is robenacoxib, a non-steroidal anti-inflammatory drug (NSAID) of the coxib class which selectively inhibits the cyclooxygenase 2 enzyme (COX-2). The tablet formulation is available in different strengths, i.e. 6 mg for cats and 5 mg, 10 mg, 20 mg and 40 mg for dogs.

The benefits of Onsior are its efficacy in the treatment of pain and inflammation in dogs and cats. The most common side effects are gastrointestinal adverse events (vomiting, soft faeces) in cats and dogs; in dogs following long-term oral treatment, an increase in liver enzyme activities was noted. The solution for injection might cause pain on injection.

The approved indications are:

Tablets
Cats: Treatment of acute pain and inflammation associated with musculo-skeletal disorders at a once daily dose of 1 mg/kg body weight up up to six days.
Dogs: Treatment of pain and inflammation associated with chronic osteoarthritis at a once daily dose of 1 mg/kg body weight as long as required (as directed by the veterinarian).

Solution for injection:
Cats: Treatment of pain and inflammation associated with soft tissue surgery.
Dogs: Treatment of pain and inflammation associated with orthopaedic or soft tissue surgery in dogs.

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 Onsior 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.

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