



Elanco Animal Health

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FOR IMMEDIATE RELEASE

Onsior® (robenacoxib) Product Line Expanded to Include Canine Soft-Tissue Surgical Pain

Elanco announces approval of oral and injectable formulations for dogs

Greenfield, Ind. (December 5, 2016) Elanco Animal Health announces the FDA approval of Onsior Tablets for Dogs and Onsior injection for the treatment of postoperative pain and inflammation associated with soft-tissue surgery in dogs aged 4 months or older and weighing 5.5 pounds (2.5 kg) or more. Veterinarians can now use the same nonsteroidal anti-inflammatory (NSAID) to manage surgical pain in both dogs and cats.

Both Onsior tablets and Onsior injection have been approved by the U.S. Food and Drug Administration (FDA) for once-daily use for a total of up to 3 days. The approved canine dose is 2 mg/kg, whether the medication is given orally or injected. Onsior Tablets are available in 10, 20 and 40 mg round, flavored tablets, while Onsior injection is available in a single, convenient formulation for both dogs and cats.

“At Elanco, we’re committed to growing our pain management portfolio, and providing veterinarians and pet owners with safe and effective solutions for companion animal analgesia,” said Dr. Tony Rumschlag, Director of Regional Consulting Veterinarians for Elanco Animal Health. “Soft-tissue surgeries, including spays and neuters, are among the most common surgical procedures performed in a veterinary hospital. Providing analgesia in conjunction with surgery provides comfort to the patient, but may also improve patient outcomes. The goal of the veterinarian is to ensure their patients’ pain is well managed so they can go home soon after their procedures and recover in surroundings that are familiar and comfortable.”

Studies support Onsior approval in canine patients

Elanco conducted a series of studies to demonstrate the safety and efficacy of Onsior in dogs. Onsior was shown to be rapidly absorbed and rapidly cleared from the bloodstream, yet it persisted at the site of inflammation.*¹

In multi-site field studies with both the oral and injectable formulations, client-owned dogs were administered Onsior in conjunction with soft-tissue procedures such as ovariohysterectomy, cystotomy, cryptorchidectomy and skin tumor removal. Onsior was administered approximately 45 minutes prior to surgery, along with a single dose of butorphanol; additional once-daily doses of Onsior were given 24 and 48 hours later.

The majority of treated dogs were evaluated as “treatment successes,” meaning that no additional analgesic medication was required to manage their pain. The study also demonstrated that Onsior was well-tolerated in dogs when used as directed. The most common adverse reactions noted during the studies were gastrointestinal signs, such as diarrhea and vomiting, while injection-site discomfort was the leading adverse reaction in dogs administered the injectable formulation.

“Many veterinarians have found Onsior to be well-suited for their spay/neuter protocols for cats,” concluded Dr. Rumschlag. “We believe this medication will also be an effective addition to canine protocols.”

*Clinical relevance unknown

Product Indications for Dogs

Onsior injection is indicated for the control of postoperative pain and inflammation associated with soft tissue surgery in dogs ≥ 4 months of age; for up to a **maximum of 3 days**.

Onsior Tablets for Dogs are approved for the control of postoperative pain and inflammation associated with soft tissue surgery in dogs ≥ 5.5 lbs (2.5 kg) **and** ≥ 4 months of age; for up to a **maximum of 3 days**.

Important Safety Information For Dogs

Do not use in dogs that have a hypersensitivity to robenacoxib or known intolerance to NSAIDs. Not for use in humans. Keep this and all drugs out of reach of children and pets. Do not use for more than 3 days. Serious adverse events have been reported with long term use in dogs. All dogs should undergo a thorough history and exam before initiation of NSAID therapy. Appropriate testing should be conducted prior to administration of an NSAID. Owners should be advised to observe for signs of potential drug toxicity. Stop administration of ONSIOR if the dog experiences inappetence, vomiting or lethargy. Safe use has not been evaluated in dogs younger than 4 months of age, dogs used for breeding, or in pregnant or lactating dogs. Do not administer in conjunction with any other NSAID or corticosteroid. For full prescribing information, call 1-888-545-5973.

Onsior injection: For subcutaneous use in dogs. Monitor dogs post-injection for reactions. Injection site reactions and anaphylactic reactions have been associated with the use of ONSIOR injection. Safety has not been demonstrated for intravenous or intramuscular administration. The most common adverse reactions were pain on injection, diarrhea and vomiting.

Onsior Tablets: For oral use in dogs only. Store out of reach of dogs and other pets in a secure location. Do not use in cats. Cats cannot be accurately dosed with the tablet sizes intended to be used in dogs. Dogs should weigh at least 5.5 lbs. The most commonly reported adverse reactions were diarrhea, vomiting, and decreased appetite.

Product Indications for Cats

Onsior injection is indicated for the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy and castration in cats ≥ 4 months of age; for up to a **maximum of 3 days**.

Onsior Tablets for Cats are indicated for the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy and castration in cats ≥ 5.5 lbs (2.5 kg) **and** ≥ 4 months of age; for up to a **maximum of 3 days**.

Important Safety Information for Cats

Do not use in cats that have hypersensitivity to robenacoxib or known intolerance to NSAIDs. All cats should undergo a thorough history and exam before initiation of NSAID therapy. Do not administer Onsior in conjunction with any other NSAID or corticosteroid. Owners should be advised to observe for signs of potential drug toxicity. For full prescribing information, call 1-888-545-5973.

Onsior injection: For subcutaneous use in cats only. The most common adverse reactions were incision site bleeding, incision site infection, vomiting, lethargy, and anorexia.

Onsior Tablets: The most common adverse events are anorexia, depression, vomiting, elevated BUN, elevated creatinine, and renal insufficiency/failure.

About Elanco Animal Health

Elanco provides comprehensive products and knowledge services to improve animal health and food-animal production in more than 70 countries around the world. We value innovation, both in scientific research and daily operations, and strive to cultivate a collaborative work environment for nearly 7,000 employees

worldwide. Together with our customers, we are committed to raising awareness about global food security, and celebrating and supporting the human-animal bond. Founded in 1954, Elanco is a division of Eli Lilly and Company. Our worldwide headquarters and research facilities are located in Greenfield, Indiana. Visit us at Elanco.com.

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about Onsior Tablets and Onsior injection as a treatment for postoperative pain and inflammation associated with soft-tissue surgery in cats and dogs, and reflects Lilly's and Elanco's current belief. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. Among other things, there can be no guarantee that Onsior will receive additional regulatory approvals or that it will be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's most recent form 10-K and form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.

1. Silber, H., Burgener, C., Letellier, I., et al. 2010. "Population pharmacokinetic analysis of blood and joint synovial fluid concentrations of robenacoxib from healthy dogs and dogs with osteoarthritis." *Pharm. Res.* 27.12: 2633-2645.

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