

Budesonide for IBD

Inflammatory bowel disease (IBD) is commonly treated with antimicrobials and immunomodulatory drugs, as well as hypoallergenic diets. The most commonly used drugs are corticosteroids, cyclosporine, and azathioprine accompanied by tylosin, oxytetracycline, or metronidazole. The most frequently used glucocorticoids in dogs with IBD are prednisone and dexamethasone. Budesonide is a nonhalogenated corticosteroid with a high affinity for glucocorticoid receptors, high hepatic clearance, and high local and low systemic activity. Budesonide could be useful for treating various forms of IBD in dogs intolerant of prednisone or dexamethasone. A drug combining potent local activity with minimal systemic effects would be beneficial in these patients.

This study evaluated the pharmacokinetics and clinical efficacy of budesonide in 11 client-owned dogs with moderate or moderate-to-severe IBD. The dogs were evaluated before treatment and on days 20 and 30 after treatment initiation. Each dog received a controlled-release formulation of budesonide (3 mg/m² PO q24h) for 30 days. Plasma and urine concentrations of budesonide and 16- α -hydroxyprednisolone were evaluated on days 1 and 8 of treatment. Budesonide was rapidly absorbed and metabolized in these dogs. Drug accumulation was gradual and an adequate therapeutic response was noted with no adverse events during the study.

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From
the Editor in
Chief

■ Commentary

Budesonide is a glucocorticoid steroid that was introduced to the human medicine market several years ago, primarily as an inhalant for treating asthma and allergic rhinitis; an oral form is also used to treat Crohn's disease (granulomatous enterocolitis-IBD). The drug has a high first pass metabolism, evading many adverse events associated with other glucocorticoids. It has been used by some veterinary gastroenterologists to treat IBD, particularly if the patient is resistant to glucocorticoid therapy or shows excessive negative steroid effects. Cyclosporine, however, is often the second line of treatment in many refractory cases. There are cost issues with both of these drugs.

What is the take-home for this study? At the dose used (3 mg/m²), the drug was effective in most dogs in this study without adverse glucocorticoid events. Should it be tried in patients resistant to dietary change, fenbendazole, and prednisone? Yes, even though it may not work in all cases for reasons discussed in the paper. However, cyclosporine may be tried first. —*Colin F. Burrows, BVetMed, PhD, Hon FRCVS, DACVIM*

■ ■ Source

Plasma concentrations and therapeutic effects of budesonide in dogs with inflammatory bowel disease. Pietra M, Fracassi F, Diana A, et al. *AM J VET RES* 74:78-83, 2013.

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OroCAM™ (meloxicam) Transmucosal Oral Spray

Non-steroidal anti-inflammatory drug for oral use in dogs only.

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

BRIEF SUMMARY: This summary does not include all the information needed to use OroCAM safely and effectively. See the Package Insert and Client Information Sheet for complete prescribing and other information.

**For Animal Use Only
For Oral Use in Dogs Only**

WARNING
Repeated use of meloxicam in cats has been associated with acute renal failure and death. Do not administer meloxicam transmucosal oral spray to cats. See Contraindications for detailed information.

Description: Meloxicam belongs to the oxicam class of non-narcotic, non-steroidal anti-inflammatory drugs (NSAID). Each milliliter of OroCAM contains 5 mg meloxicam.

Indication: OroCAM (meloxicam) Transmucosal Oral Spray is indicated for the control of pain and inflammation associated with osteoarthritis in dogs.

Dosage and Administration: Always provide the client information sheet when prescribing and dispensing OroCAM. Use the lowest effective dose for the shortest duration consistent with individual response. Due to the pump sizes, dogs weighing less than 5.5 pounds (2.5 kg) cannot be accurately dosed. OroCAM should be administered once daily at a dose of 0.1 mg/kg (0.045 mg/lb). See Bottle/Pump Assembly Instructions for Veterinarians and Administration Instructions for Owners.

Contraindications: OroCAM (meloxicam) Transmucosal Oral Spray should not be used in dogs that have a hypersensitivity to meloxicam or known intolerance to NSAIDs. Do not use OroCAM in cats.

Do not use OroCAM in cats. Acute renal failure and death have been associated with the use of meloxicam in cats.

Human Warnings: Not for use in humans. Keep this and all medications out of reach of children. Consult a physician in case of accidental ingestion by humans or contact with mucous membranes. Direct contact with skin, eyes, and mucous membranes should be avoided. If contact occurs with skin, the area should be washed immediately with soap and water for at least 20 seconds. In case of contact with eyes, flush immediately with water. Women in late pregnancy should avoid contact with this product.

Other Precautions: The use of OroCAM (meloxicam) Transmucosal Oral Spray has not been evaluated in dogs younger than 6 months of age, dogs weighing less than 5.5 lbs (2.5 kg), dogs used for breeding, or in pregnant or lactating dogs. Meloxicam is not recommended for use in dogs with bleeding disorders, as safety has not been established in dogs with these disorders. Concurrent administration of potentially nephrotoxic drugs should be carefully approached. Please refer to the full package insert for more complete information on possible interactions and other pertinent information.

Common Side Effects: The most common adverse reactions involved the gastrointestinal system (see the Table in the package insert). Non-gastrointestinal adverse reactions were rare and included increased liver enzymes, hematuria, lethargy, polydipsia, and dehydration.

The incidence of adverse reactions observed in a clinical study is tabulated in the package insert. The pattern suggests some gastrointestinal effects (vomiting, diarrhea) are associated with OroCAM. The clinical signs were generally mild, transient (lasted 1-4 days during the 28-day study period), and resulted in complete recovery. There were no clinical signs related to the increased liver enzymes.

Effectiveness: Effectiveness was demonstrated using OroCAM in a masked, placebo-controlled, multi-site field study involving client-owned dogs. In this study, 280 dogs diagnosed with osteoarthritis were randomly administered OroCAM, or a placebo. Dogs received a daily meloxicam dose or placebo for 28 days. Effectiveness was evaluated in 258 dogs and field safety was evaluated in 280 dogs. After 28 days the treatment group showed a success rate (improvement of clinical signs) of approximately 73% and the placebo group showed a success rate of about 43%.

See full Package Insert for more details, as well as for results of safety studies.

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