**NATURALS**

Historical use of one component (in this case) has been associated with acute adrenal failure and death. Do not administer to pregnant or lactating animals except under the supervision of a veterinarian. Do not give to children below the age of 6 months due to the potential for acute renal failure and death. Do not administer to animals with a history of gastrointestinal ulcerations and/or perforations, concomitant diuretic therapy, or those with existing renal, cardiovascular, or hepatic problems. NSAIDs may inhibit the prostaglandins that maintain normal homeostatic function. Such anti-prostaglandin effects are potentially nephrotoxic drugs should be carefully approached. NSAIDs may inhibit the prostaglandins that maintain normal homeostatic function. Such anti-prostaglandin effects are potentially nephrotoxic drugs should be carefully approached.

**Contraindications:**
- Do not administer to animals with bleeding disorders, except under the supervision of a veterinarian.
- Do not administer to animals with a history of acute renal failure or death.
- Do not administer to animals with existing gastrointestinal ulcerations and/or perforations, concomitant diuretic therapy, or those with existing renal, cardiovascular, or hepatic problems.
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**Precautions:**
- Carefully consider the potential benefits and risks of OroCAM (meloxicam) Transmucosal Oral Spray when administering to animals with existing renal, cardiovascular, or hepatic problems, or those on concomitant diuretic therapy.
- NSAIDs may inhibit the prostaglandins that maintain normal homeostatic function. Such anti-prostaglandin effects are potentially nephrotoxic drugs should be carefully approached.

**Adverse Reactions:**
- Mild gastrointestinal upset, anorexia, vomiting, and diarrhea have been reported in some animals treated with OroCAM (meloxicam) Transmucosal Oral Spray. These effects are typically self-limited and do not require treatment. More severe gastrointestinal effects, such as ulceration or perforation, have also been reported.

**Drug Interactions:**
- The use of concomitantly protein-bound drugs with OroCAM (meloxicam) Transmucosal Oral Spray may interfere with the absorption and therapeutic effects of other concurrently administered medications.

**Dosage and Administration:**
- Oral Spray, a non-NSAID, or non-corticosteroid class of medications, should be considered. The use of another NSAID is not recommended unless the individual patient is not a good candidate for the use of concomitantly protein-bound drugs with OroCAM (meloxicam) Transmucosal Oral Spray.

**Human Warnings:**
- OroCAM (meloxicam) Transmucosal Oral Spray is indicated for the control of pain and inflammation associated with acute renal failure and death.
- Do not administer to children below the age of 6 months due to the potential for acute renal failure and death.
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**Anatomical Therapeutic Chemical (ATC) Classification:**
- Antirheumatic anti-inflammatory agents. The influence of cyclo-oxygenase inhibitory NSAIDs as a class has not been established in dogs with these conditions. As a class, cyclo-oxygenase inhibitory NSAIDs have not been evaluated in dogs younger than 6 months of age.

**Indication:**
- OroCAM (meloxicam) Transmucosal Oral Spray is indicated for the control of pain and inflammation associated with acute renal failure and death. Do not administer to children below the age of 6 months due to the potential for acute renal failure and death.

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Transmucosal Oral Spray and contact their veterinarian immediately if any of the following occur without warning, and in rare situations, result in death:

- Vomiting; diarrohea; decreased appetite; dark or tarry stools; increased water consumption; increased urination; increased or decreased thirst;
- Physical signs such as fever, inactivity, weakness, pain, lameness, or weight loss; or
- Abnormal behavior, such as depression, excitement, or changes in normal vocalization.

OroCAM (meloxicam) Transmucosal Oral Spray has not been evaluated for use in pregnant or lactating dogs. If OroCAM (meloxicam) Transmucosal Oral Spray is used during pregnancy, or if the patient becomes pregnant while using this drug, the patient should be advised of the potential for adverse reactions in the developing fetus.

In case of overdose, contact your veterinarian immediately.

Pack 2013 A1-0068/R3 Product of Spain North Chicago, IL 60064 USA Manufactured for Abbott Laboratories respectively (same dose delivery as for OroCAM).

How Supplied:

OroCAM for trial use is supplied in the same 3 vial sizes containing 6 mL, 11 mL and 33 mL of meloxicam. Each vial has a different metered dose pump actuator. Each vial contains 400 sprays. Each spray delivers 1.25 mg of meloxicam. Each vial has a different metered dose pump actuator.

Store at controlled room temperature, between 20°-25°C (68°-77°F). Brief excursions between 15° and 30°C (59° and 86°F) are permitted.

Storage Conditions:

Meloxicam is rapidly absorbed following oral transmucosal administration. With the dose of OroCAM administered to the oral mucosa of one 5x dog.

Gross pathology revealed an ulcer in the fundic mucosa of one 2x dog, and one 3x dog. One dog in the 2x group exhibited erosions or hemorrhage in the cardia on week 26. No treatment-related lesions were seen at dosing. At baseline. Erosions or hemorrhage were noted in the pyloric antrum.

Endoscopic lesions of the pyloric antrum were seen in multiple dogs. No treatment-related lesions were seen at dosing. Erosions or hemorrhage were noted in the pyloric antrum.

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Meloxicam is eliminated principally by the liver, and to several polar metabolites. All major metabolites are eliminated in the bile (84%), whereas urine contains less than 1% of the administered radioactivity. These polar metabolites are most likely the result of sulfoxidation or glucuronidation. The systemic availability of meloxicam, as estimated from the ratio of area under the plasma concentration-time curve after intravenous and oral administration of meloxicam, was 30-50% in healthy adult dogs. Meloxicam was not detectable in plasma samples obtained from dogs after dosing OroCAM (meloxicam) Transmucosal Oral Spray.

The clinical laboratory safety study was designed to evaluate the safety of oral transmucosal administration of meloxicam in healthy adult Beagle dogs (eight dogs per group) at 1x, 2x, and 5x the recommended dose. Gastrointestinal adverse effects were the main clinical signs observed during the study. Repeated topical administration of meloxicam for 28 days to five groups of Beagle dogs was associated with the development of gastrointestinal endoscopic and histologic lesions. Gastrointestinal endoscopic and histologic lesions were not seen in the control group. There were a similar number of episodes of feces with abnormal consistency in all five groups. There were a similar number of episodes of feces with abnormal consistency in all five groups.

No treatment-related hepatic changes were noted in any group. No significant changes in serum aspartate transaminase (AST) or alanine transaminase (ALT) activity were noted in any group. There were no statistically significant differences in serum urea nitrogen, total protein, albumin, sodium, potassium, chloride, and bicarbonate concentrations between treatment groups. There was a statistically significant difference in serum chloride concentration between the placebo (vehicle) group and the 5x treatment group. The results of the clinical laboratory safety study are summarized in Table 1.