This summary contains important information about Meloxidyl® 1.5 mg/mL Oral Suspension. You should read this information before you start giving your dog Meloxidyl and review it each time the prescription is refilled. This sheet provides only as a summary and does not take the place of instructions from your veterinarian. Talk to your veterinarian if you do not understand any of this information or if you want to know more about Meloxidyl.

What is Meloxidyl?
Meloxidyl is a prescription non-steroidal anti-inflammatory drug (NSAID) that is used to control pain and inflammation (swelling) due to osteoarthritis in dogs. Osteoarthritis (OA) is a painful condition caused by the wearing down of cartilage and other parts of the joints that may result in the following changes in your dog’s behavior or signs of your dog’s discomfort (e.g., reluctance to climb or stand, stand up, climb stairs, or run, or difficulty in performing these activities) stiffness or decreased movement of joints. Meloxidyl is given to dogs by mouth. Do not use Meloxidyl Oral Suspension in cats. Acute renal failure and death have been associated with the use of meloxicam in cats.

What Kind Of Results Can I Expect When My Dog Is On Meloxidyl For OA?
While Meloxidyl is not a cure for osteoarthritis, it can control pain and inflammation associated with OA and improve your dog’s mobility.
- Response varies from dog to dog but can be quite dramatic.
- In most dogs, improvement can be seen in a matter of days.
- If Meloxidyl is discontinued or not given as directed, your dog’s pain and inflammation may come back.

What Should Dogs Not Take Meloxidyl?
Your dog should not be given Meloxidyl if he/she:
- Has had an allergic reaction to meloxicam, the active ingredient of Meloxidyl.
- Has had an allergic reaction (such as hives, facial swelling, or red or itchy skin) to aspirin or other NSAIDs.
- Is presently taking aspirin, other NSAIDs, or corticosteroids (unless directed by your veterinarian).

Meloxidyl Should Only Be Given To Dogs
People should not take Meloxidyl. Keep Meloxidyl and all medication out of reach of children. Call your veterinarian immediately if you accidentally take Meloxidyl.

How To Give Meloxidyl To Your Dog
The actual dose to be given should be prescribed by the veterinarian.

Directions for Administration:
Meloxidyl Oral Suspension is packaged with 2 sizes of dosing syringes. The small syringe (blue print) is provided for use in dogs under 15 lbs. The large syringe (green print) is provided for use in dogs 15 lbs or greater. Only administer Meloxidyl with the provided syringes. The container should never be used as a dropper bottle for administration of Meloxidyl.

**Dogs under 15 lbs (6.8 kg)**
- Shake bottle well. Push down and unscrew bottle top. Attach the dosing syringe to the bottle by gently pushing the end on to the top of the bottle.
- The daily dose (0.045 mg/lb) contains 0.03 mL of Meloxidyl Oral Suspension for every 1 lb (0.45 kg) of dog body weight.
- Replace and tighten cap after use.

**Dogs 15 lbs (6.8 kg) and over**
- Shake bottle well. Push down and unscrew bottle top. Attach the dosing syringe to the bottle by gently pushing the end on to the top of the bottle.
- The bottle/syringe is calibrated for use in dogs 15 lbs or greater. When using the small dosing syringe, the dog’s weight should be rounded down to the nearest 1 lb increment. Replace and tighten cap after use.

**Contraindications:**
- Dogs with known hypersensitivity to meloxicam should not receive Meloxidyl Oral Suspension.
- Do not use Meloxidyl Oral Suspension in cats. Acute renal failure and death have been associated with the use of meloxicam in cats.
- As with any NSAID all dogs should undergo a thorough history and physical examination before the initiation of NSAID therapy. Appropriate hematology to establish hematopoietic and serum biochemical baseline data is recommended prior to and periodically during administration. Owners should be advised to observe their dog for signs of potential drug toxicity and be given a client information sheet about Meloxidyl Oral Suspension.
- The safe use of Meloxidyl Oral Suspension in dogs younger than 6 months of age has not been established in dogs with osteoarthritis, as safety has not been established in dogs with these disorders. As a class, cyclooxygenase inhibitory NSAIDs may be associated with gastrointestinal, renal, and hepatic toxicity. Sensitivity to drug-associated adverse events varies with the individual patient. Dogs that have experienced adverse reactions from a different NSAID may experience adverse reactions from another NSAID. Patients at greatest risk for renal toxicity are those that are dehydrated, concomitantly diphtheric therapy, or those with existing renal, cardiovascular, or hepatic dysfunction. Concurrent administration of potentially nephrotoxic drugs should be carefully approached. NSAIDs may inhibit the prostaglandins that maintain normal homeostatic function. Such anti-inhibitory effects may result in clinically significant disease in patients with underlying or pre-existing disease that has not been previously diagnosed. Since NSAIDs possess the potential to induce gastrointestinal ulcerations and/or perforations, concomitant use with other anti-inflammatory drugs, such as NSAIDs or corticosteroids, should be avoided. Additional pain medication is needed after administration of the total daily dose of Meloxidyl Oral Suspension. The use of an NSAID in a non-steroidal class of analgesics should be considered. The use of another NSAID is not recommended. Consider appropriate washout times when switching from corticosteroid use or from one NSAID to another in dogs. The use of concomitantly prescribable drugs with Meloxidyl Oral Suspension has not been studied in dogs. Commonly used prescribable drugs include anticoagulants, antithrombotic, antihypertensive, and other medications. The influence of concomitant drugs that may inhibit metabolism of Meloxidyl Oral Suspension has not been established. Drug compatibility should be monitored to avoid any alteration of the therapeutic effect.

**Adverse Reactions:**
- Field safety was evaluated in 306 dogs. Based on the results of two studies, Gl abnormalities (diarrhea, epabrunner, vomiting, soft stools, diarrhea, and anorexia) were the most common adverse reactions associated with the administration of Meloxicam. The following table lists adverse reactions and the numbers of dogs that experienced them during the studies. Dogs may have experienced more than one episode of the adverse reaction during the study in some cases. For dogs 11-14 lbs, gastrointestinal ulcerations were associated with the following symptoms: vomiting, soft stools, diarrhea, and anorexia. In most dogs, improvement can be seen in a matter of days.
Drug bioavailability, volume of distribution, and total systemic clearance remain constant up to 5 times the investigator evaluation on day 7 and for the owner evaluation on day 14. Assessments of drug levels by owners included mobility, ability to rise, limping, and overall improvement. In the first field study, assessments of drug levels by veterinarians included lameness, weight-bearing, pain on palpation, and overall improvement. Parameters of the placebo-controlled, masked studies were conducted for 14 days. All dogs received 0.2 mg/kg on day 1. All dogs reached peak concentration is approximately 0.464 mcg/mL following a 0.2 mg/kg oral dose. The drug is 97% bound to plasma protein. Peak drug concentrations can be expected to occur within about 75 hrs after oral administration. Corresponding terminal elimination half-life prolongation when dogs are dosed for 45 days or longer is recommended for use in dogs. However, there is some evidence of enhanced drug accumulation and potential drug interactions with other drugs, including anticoagulants. It is recommended to avoid cumulative effects with this drug class can occur without warning and in rare situations result in death (see Adverse Reactions). Reactions have recovered when the signs are recognized, the drug is withdrawn, and veterinary care, if appropriate, is initiated. Owners should be advised of the importance of periodic follow-up for all dogs during administration of any NSAID.

Gastrointestinal: vomiting, anorexia, diarrhea, melena, gastrointestinal ulceration

Urine output, elevated creatinine, renal failure

Neurological: loss of coordination, depression, depression-induced aggression

Hepatic: elevated liver enzymes

Dermatologic: pruritus

Death has been reported as an outcome of the adverse events listed above. Acute renal failure and death have been associated with use of meloxicam in cats.

To report suspected adverse reactions, to obtain a Material Safety Data Sheet, or for technical assistance, call 1-800-999-0297. For a complete listing of adverse drug reactions for meloxicam reported to the CVM see: http://www.fda.gov/vets/irfs/AdverseEventInformation/ucm533414.htm

Information for Dog Owners: Meloxicam, like other drugs of its class, is not free from adverse reactions. Owners should be advised of the potential for adverse reactions and be informed of the clinical signs associated with drug intolerance. Adverse reactions may include vomiting, diarrhea, decreased appetite, dark or tarry stools, increased water consumption, increased urination, pale gums due to anemia, yellowing of gums, skin or white of the eye due to jaundice, lethargy, incoordination, seizure, or behavioral changes. Serious adverse reactions associated with this drug class can occur without warning and in rare situations result in death (see Adverse Reactions). Owners should be advised to discontinue Meloxicam Oral Suspension and contact their veterinarian immediately if signs of intolerance are observed. The vast majority of patients with drug-related adverse reactions have recovered when the signs are recognized, the drug is withdrawn, and veterinary care, if appropriate, is initiated. Owners should be advised of the importance of periodic follow-up for all dogs during administration of any NSAID.

Clinical Pharmacology: Meloxicam has nearly 100% bioavailability when administered orally with food. The terminal elimination half-life after a single dose is estimated to be approximately 24 hrs (-/- 30%) regardless of route of administration. There is no evidence of statistically significant gender differences in drug pharmacokinetics. Drug bioavailability, volume of distribution, and total systemic clearance remain constant up to 5 times the recommended dose for use in dogs. However, there is some evidence of enhanced drug accumulation and terminal elimination half-life prolongation when dogs are dosed for 45 days or longer. Peak drug concentrations can be expected to occur within about 7/5 hrs after oral administration. Corresponding peak concentration is approximately 0.464 mcg/mL, following a 0.2 mg/kg oral dose. The drug is 97% bound to plasma protein. Efficacy: The effectiveness of meloxicam was demonstrated in two field studies involving a total of 277 dogs representing various breeds. Between six months and sixteen years of age, all diagnosed with osteoarthritis. Both of the placebo-controlled, masked studies were conducted for 14 days. All dogs received 0.2 mg/kg on day 1. All dogs were maintained on 0.1 mg/kg oral meloxicam from days 2 through 14. Of both studies, parameters evaluated by veterinarians included lameness, weight-bearing, pain on palpation, and overall improvement. Parameters assessed by owners included mobility, ability to rise, limping, and overall improvement. In the first field study (n = 109), dogs showed clinical improvement with statistical significance after 14 days of meloxicam treatment for all parameters; however, statistical significance was demonstrated only for the overall investigator evaluation on day 7, and not for the owner evaluation on day 14.

Can Meloxicam Be Given With Other Medicines?

Meloxicam should not be given with other NSAIDs (for example, aspirin, carprofen, etodolac, deracoxib, or steroidal drugs). Consult your veterinarian before starting meloxicam if you are already taking medication for your dog. Tell your veterinarian about all medicines you have given your dog in the past, and any medicines that you are planning to give with meloxicam. This should include other medicines that you can get without a prescription. Your veterinarian may want to check that all of your dog’s medicines can be given together.

What Can I Do In Case My Dog Eats More Than The Prescribed Amount?

Contact your veterinarian immediately if your dog eats more than the prescribed amount of Meloxicam. It is important to stop therapy and contact your veterinarian immediately if you think your dog has a medical problem or side effect from Meloxicam. If you have additional questions about possible side effects, talk to your veterinarian.

What Else Should I Know About Meloxicam?

This sheet provides a summary of information about Meloxicam. If you have any questions or concerns about Meloxicam or the drug class, talk to your veterinarian.

As with all prescribed medicines, Meloxicam should only be given to the dog for which it was prescribed. Meloxicam Oral Suspension is for use in dogs only. Do not give Meloxicam to cats. It should be given to your dog only for the condition for which it was prescribed. It is important to periodically discuss your dog’s response to Meloxicam at regular checkups. Your veterinarian will best determine if your dog is responding as expected and if your dog should continue receiving Meloxicam.

For technical assistance or to report suspected adverse reactions, call 1-800-999-0297.

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