For the use only of a Registered Veterinary Practitioner, Hospital or Laboratory

METAFLAM

(Meloxicam Chewable Tablets and Oral Suspension)

Composition:
Each uncoated tablet of **METAFLAM 1mg** contains:
Meloxicam BP 1 mg
Approved flavours used.
Colours: Iron oxide Red and Iron Oxide Yellow

Each uncoated tablet of **METAFLAM 2.5mg** contains:
Meloxicam BP 2.5 mg
Approved flavours used.
Colours: Iron oxide Red and Iron Oxide Yellow

Each ml of **METAFLAM Oral Suspension** contains:
Meloxicam IP 1.5 mg
Aqueous base q.s.

Chemistry: 4-Hydroxy-2-methyl-N-(5-methylthiazol-2-yl)-2H-1,2-benzothiazine-3-carboxamide 1,1-dioxide

Category: Analgesic, Anti-inflammatory

Pharmacology
Pharmacodynamics:
Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, analgesic, anti-exudative and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it also inhibits collagen-induced thrombocyte aggregation. In vitro and in vivo studies have reported that meloxicam inhibits cyclooxygenase-2 (COX-2) to a greater extent than cyclooxygenase-1 (COX-1).

Pharmacokinetics:
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 canine plasma proteins.

Indications:
For relief of pain and inflammation in both acute and chronic musculo-skeletal disorders.

Dosage and Administration:
Meloxicam should be administered initially at 0.2 mg/kg body weight only on the first day of treatment. For all treatments after day 1, meloxicam oral suspension should be administered once daily at a dose of 0.1 mg/kg.

METAFLAM 1mg and METAFLAM 2.5mg tablets
Each chewable contains either 1 mg or 2.5 mg meloxicam, which corresponds to the daily maintenance dose for a 10 kg or a 25 kg body weight dog respectively. Each chewable tablet can be halved for accurate dosing according to the individual body weight of the animal. Meloxicam chewable tablets can be administered with or without food.

Dose scheme for the maintenance dose:

Body weight (Kg)	Number of Chewable Tablets	
	1 mg	2.5 mg
4.0 - 7.0	½	-
7.1 - 10.0	1	-
10.1 - 15.0	1½	-
15.1 - 20.0	2	-
20.1 - 25.0		1
25.1 - 35.0		1½
35.1 - 50.0		2

A clinical response is usually seen within 3-4 days. Treatment should be discontinued after 10 days at the latest if no clinical improvement is apparent.

METAFLAM Oral Suspension
Dose regimen of METAFLAM Oral Suspension
Day 0: 0.2 mg meloxicam/kg bodyweight on the first day
Maintenance dose: 0.1 mg meloxicam/kg bodyweight

Metaflam oral suspension can be given as per the recommended dosage regimen:

Day 0 0.2 mg meloxicam/kg bw		Maintenance Dose 0.1 mg meloxicam/kg bw	
Dose (ml)	Wt (kg)	Dose (ml)	Wt (kg)
0.25	1.90	0.25	3.75
0.30	2.25	0.30	4.50
0.50	3.75	0.50	7.50
0.60	4.50	0.60	9.00
1.00	7.50	1.00	15.00
1.50	11.25	1.50	22.50
2.00	15.00	2.00	30.00
2.50	18.75	2.50	37.50
3.00	22.50	3.00	45.00
3.50	26.25	3.50	52.50
4.00	30.00	4.00	60.00
4.50	33.75	4.50	67.50
5.00	37.50	5.00	75.00

Directions for Administration of METAFLAM Oral Suspension:
Shake well before use, then remove cap. Particular care should be given with regard to the accuracy of dosing. To prevent accidental overdosing of small dogs, administer drops on food only, never directly into the mouth. Carefully measure suspension onto food to assure that the correct dose is given before presentation of the food to the dog.

Warning and Precautions:
Not for use in humans. Keep out of reach of children. Consult a physician in case of accidental ingestion by humans. For oral use in dogs only. As with any NSAIDs all dogs should undergo a thorough history and physical examination before the initiation of NSAIDs therapy.

Dogs with known hypersensitivity to meloxicam should not receive meloxicam oral suspension. Appropriate laboratory testing to establish hematological and serum biochemical baseline data is recommended prior to and periodically during administration. Owner should be advised to observe their dog for signs of potential drug toxicity.

Precautions:
The safe use of meloxicam oral suspension in dogs younger than 6 weeks of age, dogs used for breeding, or in pregnant or lactating bitches has not been evaluated. Meloxicam is not recommended for use in dogs with bleeding disorders, 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. Patients at greatest risk for renal toxicity are those that are dehydrated, on concomitant diuretic therapy, or those with existing renal, cardiovascular, and/or hepatic dysfunction. Concurrent administration of potentially nephrotoxic drugs should be carefully approached. Since many NSAIDs possess the potential to produce gastrointestinal ulceration, concomitant use of meloxicam oral suspension with other anti-inflammatory drugs, such as NSAIDs or corticosteroids, should be avoided or closely monitored. Consider appropriate washout times when switching from corticosteroid use or from one NSAIDs to another in dogs. The use of concomitantly protein-bound drugs with meloxicam oral suspension has not been studied in dogs. Commonly used protein-bound drugs include cardiac, anticonvulsant and behavioral medications. The influence of concomitant drugs that may inhibit metabolism of meloxicam oral suspension has not been evaluated. Drug compatibility should be monitored in patients requiring adjunctive therapy.

Interactions:
Combinations containing any of the following medications, depending on the amount present, may also interact with this medication.

Anticoagulants: Because nonsteroidal anti-inflammatory drugs [NSAIDs] have been associated with inhibition of platelet aggregation and with the potential for gastrointestinal ulceration or bleeding, concurrent administration with an anticoagulant could increase the risk of adverse effects; however, studies in dogs have indicated that effects on thromboxane A2 [as measured by thromboxane B2] are minimal, making antiplatelet effects unlikely when administered at recommended dosages; also, it has been reported that no change in buccal mucosal bleeding time occurs in healthy dogs with a single 0.2 mg/kg dose. Anti-inflammatory drugs, nonsteroidal (NSAIDs) or Corticosteroids: Concurrent administration of more than one NSAIDs or of corticosteroids with a NSAIDs may greatly increase the risk of adverse effects. Diuretics: Animals on diuretic therapy could have an increased risk of renal toxicity with NSAIDs administration.

Nephrotoxic medications: NSAIDs have been associated with renal toxicity; therefore, administration with other nephrotoxic medications should be viewed with caution.

Pregnancy and Lactation:
The safety of administering meloxicam to dogs during breeding, pregnancy or lactation has not been studied.

Adverse drug reactions:
In most cases, adverse effects were transient and disappeared after termination of treatment. In rare cases however, death has been associated with some of these adverse reactions. The following suspected adverse effects have been reported:
Gastrointestinal: Vomiting, diarrhea, inappetence, melena, hematemesis, ulceration.
Central Nervous System/Behavioral: Ataxia, seizures, sleepiness, hyperactivity, depression, trembling.
Renal: Elevated creatinine and BUN, acute renal failure.
Dermatologic: Pruritus, eczema, focal alopecia, moist dermatitis (hot spots).
Hypersensitivity: Urticaria, allergic dermatitis.
Hematologic: Immune mediated hemolytic anemia, immune mediated thrombocytopenia.
Hepatic: Elevated liver enzymes, jaundice.
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 Drug Reactions). Owners should be advised to discontinue meloxicam 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 NSAIDs.

Overdosage:
In case of overdosing, symptomatic treatment should be initiated.

Presentation: Bottle of 15ml with dropper

Storage: Store protected from Light and moisture, at a temperature not exceeding 30°C.
Keep out of reach of children
SHAKE WELL BEFORE USE.

For oral use in dogs.

Last update: October 2023.

SAVAVET
Shaping the Future

SAVA HEALTHCARE LIMITED
Plot No. 507-B to 512 GIDC Estate,
Wadhwan City – 363035, Surendranagar,
Gujarat, India
www.savavet.com