MELLIS® VET

MFI OXICAM

VETERINARY USE

Non-Steroidal Anti-Inflammatory Agent For Oral Use in Dogs

Formula

| Each Mellis® Vet 0.5 mg tablet contains: | |
|--|--------|
| Meloxicam | 0,5 mg |
| Excipients q.s.p. | 70 mg |
| Each Mellis® Vet 2.0 mg tablet contains: | |
| Meloxicam | 2,0 mg |
| Excipients q.s.p. | 280 mg |
| Each Mellis® Vet 3.0 mg tablet contains: | |
| Meloxicam | 3,0 mg |
| Excipients q.s.p. | 420 mg |
| Each Mellis® Vet 4.0 mg tablet contains: | _ |
| Meloxicam | 4,0 mg |
| Excipients q.s.p. | |

Technical Information

Meloxicam is a non-steroidal anti-inflammatory drug (NSAID), a preferential cyclooxygenase-2 (COX2) inhibitor, belonging to the oxicam class. It inhibits the production of the prostaglandins involved in the inflammatory process. It has analgesic, anti-pyretic and anti-inflammatory properties. It is rapidly absorbed orally, achieves adequate plasma peak in up to 7 hours and can be administered with food, once daily. Meloxicam is eliminated in inactive form in feces, urine and bile.

Indications:

Mellis® Vet is indicated as an analgesic and anti-inflammatory agent for dogs.

THE EFFICACY OF THIS PRODUCT HAS NOT BEEN INVESTIGATED BY THE MINISTRY OF AGRICULTURE. LIVESTOCK AND SUPPLY (MAPA).

Dosage and how to use

Mellis® Vet should only be administered orally. The recommended dose is 0.2 mg/kg at the first dose, followed by 0.1 mg/kg every 24 hours for up to 13 days, according to the table below:

| Animal weight in kg | First day 0.2 mg/kg, once daily | Second day forward 0.1 mg/kg, once daily |
|---------------------|------------------------------------|---|
| 5 kg | Two 0.5 mg tablets | One 0.5 mg tablet |
| 10 kg | One 2.0 mg tablet | ½ tablet of 2.0 mg |
| 15 kg | One 3.0 mg tablet | ½ tablet of 3.0 mg |
| 20 kg | One 4.0 mg tablet | ½ tablet of 4.0 mg |
| 30 kg | Two 3.0 mg tablets | One 3.0 mg tablet |
| 40 kg | Two 4.0 mg tablets | One 4.0 mg tablet |

According to the efficacy study conducted in dogs, Mellis® Vet showed to be 100% effective for the relief of acute pain and inflammation, when administered at the initial dose of 0.2 mg/kg (Day 1), followed by the 0.1 mg/kg dose on subsequent days, every 24 hours, for 7 days, in female dogs undergoing ovary-salpingo-hysterectomy (OSH). Treatment can be extended up to the 13th Day, according to the results obtained in the safety study conducted with the product.

Contraindications

The product should not be given to dogs with hypersensitivity to meloxicam or any of the components of the formula. It is not recommended for pregnant, lactating female dogs, and dogs under 12 months of age, as no study was conducted in these groups. Mellis® Vet, like all non-steroidal anti-inflammatory drugs, is not recommended for dogs presenting bleeding disorders, cardiovascular diseases, hepatic, renal and gastrointestinal disorders, nor for dehydrated, hypovolemic and hypotensive animals.

Drug interactions

The concomitant use of Mellis® Vet with anticoagulants, other steroidal or nonsteroidal anti-inflammatory drugs, diuretics, angiotensin-converting enzyme inhibitors (ACEI) and potentially nephrotoxic agents must be avoided due to the increased risk of adverse effects.

Adverse effects

Mellis® Vet showed to be safe in a safety study conducted in dogs, when administered at the recommended doses, for up to 13 consecutive days. During this period, no changes were observed in hematological and biochemical tests. Reactions such as emesis, mild to moderate abdominal pain, hyporexia and bloody stools may occur, but at a low incidence when the drug is administered as recommended in the leaflet. When used in overdose and for longer than indicated, it can cause apathy, mild to severe abdominal pain, emesis, changes in stool consistency, hyporexia and melena.

Precautions

The safety of Mellis® Vet has not been investigated in pregnant or lactating female dogs, in animals used for breeding, and those under 1 year of age.

Poisoning and overdose

In cases of poisoning or overdose, seek the advice of a Veterinary doctor for evaluation and supportive treatment. Reactions such as apathy, mild to severe abdominal pain, emesis, changes in stool consistency, hyporexia and melena have been observed in dogs receiving twice the maximum recommended therapeutic dose.

Warnings

Veterinary products must be kept out of the reach of children and pets. They should not be stored near food, drinks or personal hygiene products. No safety studies have been conducted in dogs under 1 year of age, nor in pregnant and lactating female dogs.

Presentation

Blister with 10 bisected tablets.

Blister with 4 bisected tablets (FREE SAMPLE).

Storage recommendations

Keep the product in a dry place, at room temperature (15oC to 30oC), away from direct sunlight and out of the reach of children and pets. In case of accidental ingestion, seek medical attention and take the product package with you.

Lot, manufacturing and expiration date: see packaging.

SALE UNDER THE VETERINARIAN'S PRESCRIPTION AND APPLICATION.

Product provisionally licensed in the Ministry of Agriculture, Livestock and Supply under no 21/2020 on 1/29/2020.

Owner and manufacturer:

Biolab Sanus Farmacêutica Ltda.

Av. Francisco Samuel Lucchesi Filho, 1039 Bragança Paulista - SP CEP: 12929-600 - CNPJ: 49.475.833/0018-46 - SAC: 0800 941 5566

Responsible technician: Daniela Ziolkowski, CRF-SP 29.486.

Expiry date: 24 months after the manufacturing date.

