

PACKAGE LEAFLET
Adocam 1.5 mg/ml Oral Suspension for dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder

ES:

Laboratorios Calier, S.A.
C/. Barcelonés, 26 (Pla del Ramassà)
08520 Les Franqueses des Valles (Barcelona)
Spain

PT:

Calier Portugal, S.A.
Centro Empresarial Sintra Estoril II, Edificio C
Rua Pé de Mouro
Estrada de Albarraque
2710 – 335 Sintra
Portugal

Manufacturer responsible for batch release:

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Adocam 1.5 mg/ml Oral Suspension
Meloxicam

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains:

Active substance:

Meloxicam 1.5 mg

Excipient:

Sodium benzoate 1.5 mg

Adocam 1.5 mg/ml Oral Suspension is a pale yellow viscous suspension.

4. INDICATION(S)

Meloxicam is a Non-Steroidal Anti-Inflammatory Drug (NSAID) that alleviates inflammation and pain in both acute and chronic musculo-skeletal disorders.

5. CONTRAINDICATIONS

- Do not use in pregnant or lactating animals.
- Do not use in animals suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders
- Do not use in cases of known hypersensitivity to the active substance or to any of the excipients.
- Do not use in dogs less than 6 weeks of age.

6. ADVERSE REACTIONS

Typical adverse drug reactions of NSAIDs such as loss of appetite, vomiting, diarrhoea, faecal occult blood and apathy have occasionally been reported. These side effects occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage

Initial treatment is a single dose of 0.2 mg meloxicam/kg body weight on the first day. Treatment is to be continued once daily by oral administration (at 24-hour intervals) at a maintenance dose of 0.1 mg meloxicam/kg body weight.

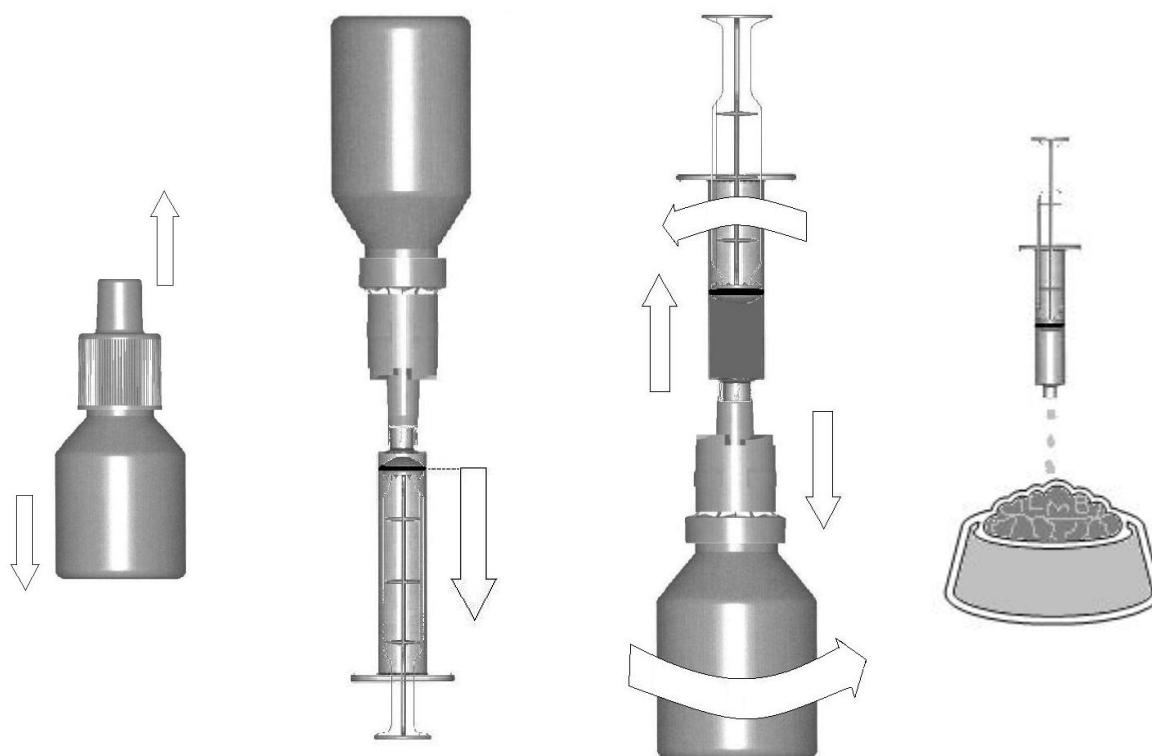
Method and route of administration

Shake well before use.

To be administered mixed with food.

Particular care should be taken with regard to the accuracy of dosing.

The suspension can be given using the measuring syringe provided in the package (see below). The syringe fits onto the bottle and has a kg-body weight scale which corresponds to the maintenance dose (i.e. 0.1 mg meloxicam/kg body weight). Thus for the first day, twice the maintenance volume will be required.



Shake bottle well. Push down and unscrew bottle top. Attach the dosing syringe to the bottle by gently pushing the end onto the top of the bottle.

Turn the bottle/syringe upside down. Pull the plunger out until the black line on the plunger corresponds to your dog's bodyweight in kilograms

Turn the bottle right way up and with a twisting movement separate the dosing syringe from the bottle

Empty the contents of the syringe onto the food by pushing the plunger in.

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

For longer term treatment, once clinical response has been observed (after ≥ 4 days), the dose of the veterinary medicinal product can be adjusted to the lowest effective individual dose reflecting that the degree of pain and inflammation associated with chronic musculo-skeletal disorders may vary over time.

9. ADVICE ON CORRECT ADMINISTRATION

Particular care should be taken with regard to the accuracy of dosing. Please carefully follow the instructions of the veterinarian.

The date of first use (on first opening of the bottle) should be recorded on the space provided on the label, along with the expiry date of the opened bottle (six months from the date of opening). Any unused veterinary medicinal product should be discarded after this date.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

The veterinary medicinal product does not require any special storage conditions.

After each dose, the tip of the syringe should be wiped and the bottle cap screwed back on tightly. The syringe should be stored in the carton box in between uses.

Do not use this veterinary medicinal product after the expiry date stated on the carton and the bottle after EXP. The expiry date refers to the last day of that month.

Shelf-life after first opening the container: 6 months.

Following withdrawal of the first dose, use the product within 6 months. Any product remaining after this period should be discarded. The discard date should be calculated and written in the space provided on the label.

12. SPECIAL WARNING(S)

Special precautions for use in animals

If side effects occur, treatment should be discontinued and the advice of a veterinarian should be sought. Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity.

Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects. Meloxicam must not be administered in conjunction with other NSAIDs or glucocorticosteroids.

Pre-treatment with anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such drugs should be observed for at least 24 hours before commencement of treatment. The treatment-free period, however, should take into account the pharmacokinetic properties of the products used previously.

In the case of overdosage symptomatic treatment should be initiated.

Special Precautions to be taken by the person administering the veterinary medicinal product to animals

People with known hypersensitivity to NSAIDs should avoid contact with the veterinary medicinal product.

In case of accidental ingestion, seek medical advice immediately and show this package leaflet or the label to the physician.

Wash any splashes from skin immediately with water.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Package sizes:

Bottles of 10 ml, 25 ml, 50 ml or 125 ml in a cardboard box.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder

BLUE BOX REQUIREMENTS

Portugal (PT)

Legal Status

Só pode ser vendido mediante receita médica veterinária [= *prescription only*]