PARTICULARS TO APPEAR ON THE OUTER PACKAGE (CARDBOARD CARTON)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Adocam 1.5 mg/ml Oral Suspension for dogs
Meloxicam

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance:
Meloxicam 1.5 mg (equivalent to 0.05 mg per drop)

3. PHARMACEUTICAL FORM

Oral Suspension

4. PACKAGE SIZE

10 ml bottle
32 ml bottle
100 ml bottle

A measuring device (a plastic syringe) is also included in the pack.

5. TARGET SPECIES

For dogs
(a pictogram may be used in addition to the wording)

6. INDICATION(S)

Not applicable – immunologicals only

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.
To be administered mixed with food.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not Applicable

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the immediate packaging: 6 months
Once opened, use by: ……..

11. SPECIAL STORAGE CONDITIONS

Do not store above 30ºC.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: See package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

IE, UK:
aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

ES:
Laboratorios Calier, S.A.
Calle Barcelones 26
08520 Les Franqueses des Valles (Barcelona)
Spain

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

16. MARKETING AUTHORISATION NUMBER

Vm 24745/4024

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

BLUE BOX REQUIREMENTS

United Kingdom (UK)

Legal Status
Medicines may only be prescribed by a registered veterinary surgeon. The prescription may be dispensed by any registered veterinary surgeon or registered pharmacist.

POM-V

Additional Information
UK Authorised Veterinary Medicinal Product
Keep the container in the outer carton

Ireland (IE)

Additional Information
Abbreviation for route of sale and supply to be placed in box
National waste disposal requirements, as necessary

POM

Portugal (PT)

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

Additional Information

Uso Veterinário

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS (10 ml and 32 ml)

VIA ADHESIVE LABEL ON BOTTLE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Adocam 1.5 mg/ml Oral Suspension for dogs

Meloxicam

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 1.5 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml
32 ml
100 ml

4. ROUTE(S) OF ADMINISTRATION

Shake well before use.
To be administered mixed with food.

5. WITHDRAWAL PERIOD

Not applicable

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Once opened, use by:……

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON IMMEDIATE PACKAGE (100 ml)

VIA ADHESIVE LABEL ON BOTTLE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Adocam 1.5 mg/ml Oral Suspension for dogs
Meloxicam

2. STATEMENT OF ACTIVE

Active substance:
Meloxicam 1.5 mg (equivalent to 0.05 mg per drop)

3. PHARMACEUTICAL FORM

Oral Suspension

4. PACKAGE SIZE

10 ml bottle
32 ml bottle
100 ml bottle

A measuring device (a plastic syringe) is also included in the pack.

5. TARGET SPECIES

For dogs
(a pictogram may be used in addition to the wording)

6. INDICATION(S)

Not applicable – immunologicals only

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.
To be administered mixed with food.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not Applicable

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened, use by:……..

11. SPECIAL STORAGE CONDITIONS

Do not store above 30ºC.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: See package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

IE, UK
aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

ES:
Laboratorios Calier, S.A.
Calle Barcelones 26
08520 Les Franqueses des Valles (Barcelona)
Spain

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

16. MARKETING AUTHORISATION NUMBER

Vm 24745/4024

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

BLUE BOX REQUIREMENTS

United Kingdom (UK)

Legal Status
Medicines may only be prescribed by a registered veterinary surgeon. The prescription may be dispensed by any registered veterinary surgeon or registered pharmacist.

POM-V

Additional Information
UK Authorised Veterinary Medicinal Product
Keep the container in the outer carton

Ireland (IE)

Additional Information
Abbreviation for route of sale and supply to be placed in box
National waste disposal requirements, as necessary

POM

Portugal (PT)

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

Additional Information

Uso Veterinário

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

IE, UK:
aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

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, Edifício 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 of suspension contains:

Active substance:
Meloxicam 1.5 mg (equivalent to 0.05 mg per drop)

Excipient:
Sodium benzoate 1.5 mg (equivalent to 0.05 mg per drop)
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

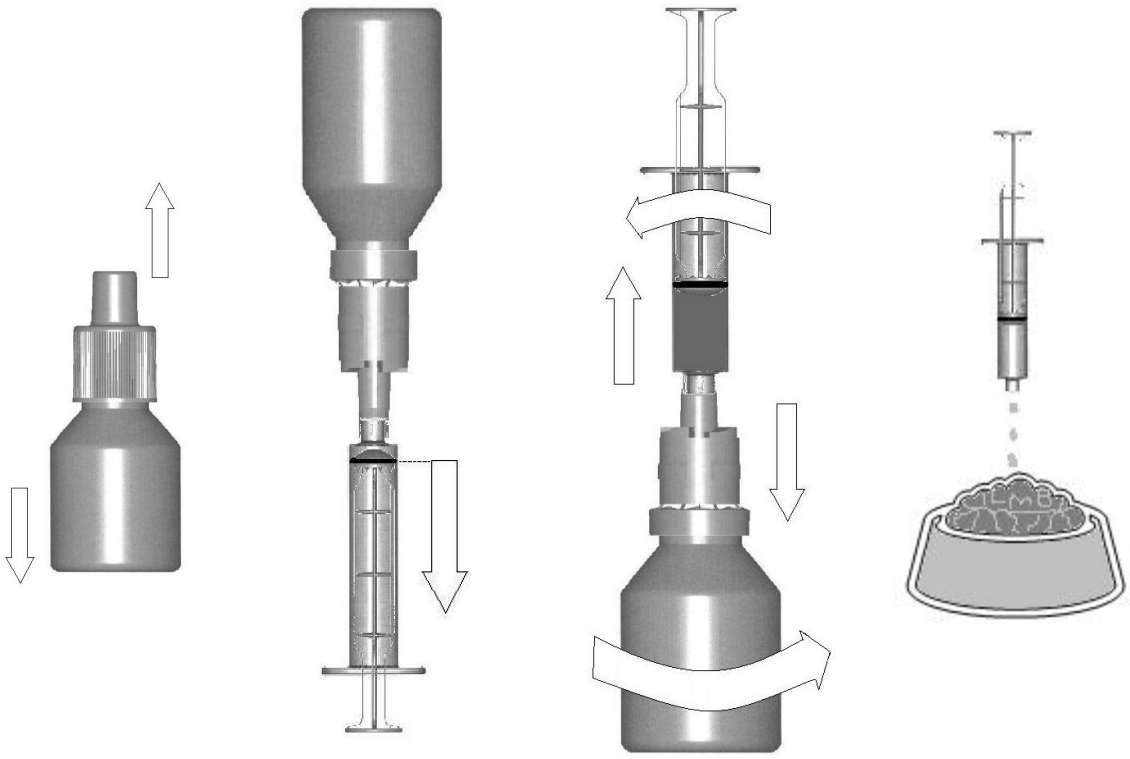
Dosage
Initial treatment is a single dose of 0.2 mg meloxicam/kg body weight on the first day. Treatment is to be continued once daily by oral administration (at 24-hour intervals) at a maintenance dose of 0.1 mg meloxicam/kg body weight.

Method and route of administration
Shake well before use. To be administered mixed with food.

The suspension can be given using either the drop dispenser (for very small breeds) or the measuring syringe provided in the package (see below).

The dispenser provides 0.05 mg meloxicam per drop (i.e. a dose of 0.1 mg meloxicam/kg body weight corresponds to 2 drops/kg body weight).

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.

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.

Do not store above 30ºC.

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.

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

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.

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

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

10, 32 or 100 ml bottle. 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

United Kingdom (UK)

Legal Status
Medicines may only be prescribed by a registered veterinary surgeon. The prescription may be dispensed by any registered veterinary surgeon or registered pharmacist.

POM-V

Additional Information
UK Authorised Veterinary Medicinal Product
Keep the container in the outer carton

Ireland (IE)

Identification
Veterinary Product Authorisation (VPA) number (10776/001/001)

Additional Information
Abbreviation for route of sale and supply to be placed in box and explanatory phrase
National waste disposal instructions, as appropriate.

POM — Prescription Only Medicine

Portugal (PT)

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

Approved 11 October 2022