PARTICULARS TO APPEAR ON THE OUTER PACKAGE	PARTICULARS TO	APPEAR ON TH	HE OUTER PAG	CKAGE
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{Carton for 15 ml, 42 ml, 100 ml or 200 ml bottle}

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Movocam 1.5 mg/ml oral suspension for dogs

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Meloxicam 1.5 mg/ml

## 3. PACKAGE SIZE

15 ml 42 ml 100 ml 200 ml

## 4. TARGET SPECIES

Dogs.

## 5. INDICATIONS

## 6. ROUTES OF ADMINISTRATION

Shake well before use.

To be administered mixed with food or directly into the mouth.

Read the package leaflet before use.

## 7. WITHDRAWAL PERIODS

## 8. EXPIRY DATE

EXP {mm/yy}

Once opened use within 6 months. Use by...

## 9. SPECIAL STORAGE PRECAUTIONS

## 10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

## 11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

## 12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

#### 13. NAME OF THE MARKETING AUTHORISATION HOLDER

**EU Pharmaceuticals Ltd** 

Distributed in the United Kingdom by CHANELLE VET UK LTD, 483 Green Lanes, London, N13 4BS

## 14. MARKETING AUTHORISATION NUMBER

Vm 39787/5015

## 15. BATCH NUMBER

BN{number}

## 16. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

# 17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

# 18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE [Distribution category]

POM-V Veterinary medicinal product subject to prescription.

## PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{Label for 100 ml and 200 ml bottles}

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Movocam 1.5 mg/ml oral suspension for dogs

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Meloxicam 1.5 mg/ml

## 3. TARGET SPECIES

Dogs.

#### 4. ROUTES OF ADMINISTRATION

Shake well before use.

Avoid introduction of contamination during use.

To be administered mixed with food or directly into the mouth.

Read the package leaflet before use.

## 5. WITHDRAWAL PERIODS

## 6. EXPIRY DATE

EXP {mm/yy}

Once opened use within 6 months. Use by...

## 7. SPECIAL STORAGE PRECAUTIONS

## 8. NAME OF THE MARKETING AUTHORISATION HOLDER

**EU Pharmaceuticals Ltd** 

Distributed in the United Kingdom by CHANELLE VET UK LTD, 483 Green Lanes, London, N13 4BS

## 9. BATCH NUMBER

BN{number}

## 10. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

# 11. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

12. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE [Distribution category]

For animal treatment only.

POM-V Veterinary medicinal product subject to prescription.

## MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Label for 15 ml and 42 ml bottle}

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Movocam 1.5 mg/ml oral suspension for dogs

# 2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

Meloxicam 1.5 mg/ml

## 3. BATCH NUMBER

BN {number}

## 4. EXPIRY DATE

EXP {mm/yy}

Once opened use within 6 months.

## 5. ROUTE(S) OF ADMINISTRATION

Shake well before use.

To be administered mixed with food or directly into the mouth.

## 6. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

## **B. PACKAGE LEAFLET**

## **PACKAGE LEAFLET:**

Movocam 1.5 mg/ml oral suspension for dogs

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Movocam 1.5 mg/ml oral suspension for dogs

## 2. COMPOSITION

Each ml contains:
<a href="Active substance">Active substance</a>
Meloxicam 1.5 mg

Excipient Sodium benzoate 5 mg

A yellow coloured suspension

## 3. TARGET SPECIES

Dogs.

## 4. INDICATIONS FOR USE

Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs.

#### 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 known cases of hypersensitivity.

Do not use in dogs less than 6 weeks of age.

## 6. SPECIAL WARNINGS

Special precautions for use in animals:

Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of renal toxicity.

This product for dogs should not be used in cats as it is not suitable for use in this species.

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

People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the veterinary medicinal product.

Accidental ingestion of the product by a child may cause gastro-intestinal effects, such as nausea and gastric pain.

Any uneaten medicated food must be disposed of immediately and the bowl washed thoroughly.

Do not leave an unattended filled syringe in the sight or reach of children.

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

This product can cause eye irritation. In case of contact with the eyes, immediately rinse thoroughly with water.

## Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation (see section 'Contraindications').

## Interaction with other medicinal products and other forms of interaction:

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 veterinary medicinal products should be observed for at least 24 hours before commencement of treatment. The treatment-free period, however, should take into account the pharmacological properties of the veterinary products used previously.

## Overdose (symptoms, emergency procedures, antidotes):

In the case of overdosage symptomatic treatment should be initiated.

## Major Incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

#### 7. ADVERSE EVENTS

#### Dogs.

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Appetite loss*, Lethargy* Renal failure* Vomiting*, Diarrhoea*, Blood in faeces*, Gastrointestinal ulceration, Haemorrhagic diarrhoea, Haematemesis Elevated liver enzymes
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<sup>\*</sup> Typical adverse reactions of NSAIDs

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.

If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system <a href="https://www.gov.uk/report-veterinary-medicine-problem">https://www.gov.uk/report-veterinary-medicine-problem</a>

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

Shake well before use. To be administered mixed with a small amount of food, or directly into the mouth.

Avoid introduction of contamination during use.

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. For longer term treatment, once clinical response has been observed (after ≥ 4 days), the dose 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.

The suspension can be given using the measuring syringes provided in the package. The appropriate syringe should be used depending on the body weight of the animal (small syringe for dogs up to 20 kg body weight, larger syringe for dogs 20 – 60 kg body weight). The syringes fit onto the bottle and have a kg-body weight scale which corresponds to the maintenance dose volume required (i.e. 0.1 mg meloxicam/kg body weight).

The following dosing table indicates what volume to administer depending on the weight of the dog:

Bodyweight (kg)	Maintenance dosage (ml)
7.5	0.5
15	1
22.5	1.5
30	2
37.5	2.5
45	3
52.5	3.5
60	4

For the first day, twice the maintenance dosage will be required.

A clinical response is normally seen within 3 to 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.

## 10. WITHDRAWAL PERIOD(S)

Not applicable.

## 11. SPECIAL STORAGE PRECAUTIONS

This veterinary medicinal product does not require any special storage conditions. Keep out of the sight and reach of children.

Do not use after the expiry date (EXP) stated on the carton and the bottle. Once opened use within 6 months.

## 12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

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

These measures should help to protect the environment.

#### 13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription

## 14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 39787/5015

15, 42, 100 or 200 ml bottle with two measuring syringes. Not all pack sizes may be marketed.

## 15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

## 16. CONTACT DETAILS

## Marketing authorisation holder

EU Pharmaceuticals Ltd 37 Geraldine Road London SW18 2NR

## Manufacturer responsible for batch release and contact details to report suspected adverse reactions

Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea,
Co. Galway,
IRELAND.

Telephone: +353 (0)91 841788

vetpharmacoviggroup@chanellegroup.ie

<u>Distributed in the United Kingdom by</u> CHANELLE VET UK LTD, 483 Green Lanes, London, N13 4BS

## 17. OTHER INFORMATION

POM-V Veterinary medicinal product subject to prescription.

For animal treatment only

Approved 26 October 2023

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