ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Arthrocam 0.5 mg/ml oral suspension for cats

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Meloxicam 0.5 mg/ml

3. PACKAGE SIZE

3 ml
5 ml
10 ml
15 ml

4. TARGET SPECIES

Cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Shake well before use.
Oral use.
Read the package leaflet before use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

EXP {mm/yy}
3 ml: Once opened use within 14 days.
5 ml: Once opened use within 14 days.
10 ml: Once opened use within 6 months.

15 ml: 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 39787/5012

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.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Arthrocam 0.5 mg/ml oral suspension for cats

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE

Meloxicam 0.5 mg/ml

3. BATCH NUMBER

BN {number}

4. EXPIRY DATE

EXP {mm/yy}

3 ml	Once opened use within 14 days.
5 ml	Once opened use within 6 months.
10 ml:	Once opened use within 6 months.
15 ml:	Once opened use within 6 months.

5. ROUTE OF ADMINISTRATION

Oral use

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Arthrocam 0.5 mg/ml oral suspension for cats

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Arthrocam 0.5 mg/ml oral suspension for cats

2. COMPOSITION

One ml contains:

Active substance
Meloxicam 0.5 mg.

Excipient
Sodium benzoate 1.5 mg.

Smooth light yellow suspension.

3. TARGET SPECIES

Cats

4. INDICATIONS FOR USE

Alleviation of mild to moderate post-operative pain and inflammation following surgical procedures in cats, e.g. orthopaedic and soft tissue surgery.
Alleviation of pain and inflammation in acute and chronic musculo-skeletal disorders in cats.

5. CONTRAINDICATIONS

Do not use in pregnant or lactating animals.
Do not use in cats suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in cats 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 increased renal toxicity.

Post-operative use:
In case additional pain relief is required, multimodal pain therapy should be considered.

Chronic musculoskeletal disorders:
Response to long-term therapy should be monitored at regular intervals by a veterinary surgeon.

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 this 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:
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.
Arthrocam must not be administered in conjunction with other NSAIDs or glucocorticosteroids. Concurrent administration of potential nephrotoxic veterinary medicinal products should be avoided.

In cats, 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 products used previously.

Overdose (symptoms, emergency procedures, antidotes):
Meloxicam has a narrow therapeutic safety margin in cats and clinical signs of overdose may be seen at relatively small overdose levels.
In case of overdose, adverse reactions, as listed in section "Adverse reactions", are expected to be more severe and more frequent. In case of overdose 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

Cats.

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Appetite loss*, Lethargy* Renal failure* Vomiting*, Diarrhoea*, Blood in faeces* Gastrointestinal ulceration Elevated liver enzymes.

* Typical adverse reactions of NSAIDs

These side effects 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 https://www.gov.uk/report-veterinary-medicine-problem

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

Oral use.

Post-operative pain and inflammation following surgical procedures:
After initial treatment with a suitable 5 mg/ml meloxicam solution for injection for cats, continue treatment 24 hours later with Arthrocam 0.5 mg/ml oral suspension for cats at a dosage of 0.05 mg meloxicam/kg body weight (0.1 ml /kg). The oral follow-up dose may be administered once daily (at 24-hour intervals) for up to four days.

Acute musculo-skeletal disorders:
Initial treatment is a single oral dose of 0.2 mg meloxicam/kg body weight (0.4 ml/kg) on the first day. Treatment is to be continued once daily by oral administration (at 24-hour intervals) at a dose of 0.05 mg meloxicam/kg body weight (0.1 ml /kg) for as long as acute pain and inflammation persist.

Chronic musculo-skeletal disorders:
Initial treatment is a single oral dose of 0.1 mg meloxicam/kg body weight (0.2 ml/kg) on the first day. Treatment is to be continued once daily by oral administration (at 24-hour intervals) at a maintenance dose of 0.05 mg meloxicam/kg body weight (0.1 ml /kg). A clinical response is normally seen within 7 days. Treatment should be discontinued after 14 days at the latest if no clinical improvement is apparent.

Route and method of administration
A one ml syringe is provided with the product. To be administered orally either mixed with food or directly into the mouth. Particular care should be taken with regard to the accuracy of dosing. The recommended dose should not be exceeded.

9. ADVICE ON CORRECT ADMINISTRATION

Please carefully follow the instructions of the veterinarian.
Shake well before use.
Avoid introduction of contamination during use.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the bottle after EXP.
Shelf life after first opening of the container:
3 ml and 5 ml bottles: 14 days
10 ml and 15 ml bottles: 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 39787/5012

Pack size: 1 x 3 ml, 1 x 5 ml 1 x 10 ml or 1 x 15 ml bottle with a measuring syringe.

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

Distributed in the United Kingdom by
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 02 February 2024