SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Arthrocam 0.5 mg/ml oral suspension for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:
Active substance
Meloxicam 0.5 mg

Excipient
Sodium benzoate 1.5 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension.
A smooth light yellow suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cats

4.2 Indications for use, specifying the target species

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.

4.3 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 known cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in cats less than 6 weeks of age.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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

Special precautions for the protection of the environment:
Not applicable.

Other precautions:
Not applicable.

4.6 Adverse reactions (frequency and seriousness)

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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder, or the national competent authority via the national reporting system. See also section 16 of the package leaflet for contact details.

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation (see section 4.3).

4.8 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 drugs 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.

4.9 Amounts to be administered and administration route

Oral use.

<u>Post-operative pain and inflammation following surgical procedures:</u>
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.

<u>Acute musculo-skeletal disorders:</u>
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.

<u>Chronic musculo-skeletal disorders:</u>
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.

Advice on correct administration
Shake well before use.
Avoid introduction of contamination during use.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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 4.6, are expected to be more severe and more frequent. In case of overdose symptomatic treatment should be initiated.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-inflammatory and antirheumatic products, non-steroids (oxicams)
ATC vet code: QM01AC06

5.1 Pharmacodynamic properties

Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, analgesic, anti-exudative and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it also inhibits collagen-induced thrombocyte aggregation. *In vitro* and *in vivo* studies demonstrated that meloxicam inhibits cyclooxygenase-2 (COX-2) to a greater extent than cyclooxygenase-1 (COX-1).

5.2 Pharmacokinetic particulars

Absorption
If the animal is fasted when dosed, the maximal plasma concentrations are obtained after approximately 3 hours. If the animal is fed at the time of dosing, the absorption may be slightly delayed.

Distribution
There is a linear relationship between the dose administered and plasma concentration observed in the therapeutic dose range. Approximately 97% of meloxicam is bound to plasma proteins.

Metabolism
Meloxicam is predominantly found in plasma and is also a major biliary excretion product whereas urine contains only traces of the parent compound. Five major metabolites were detected all having been shown to be pharmacologically inactive. Meloxicam is metabolised to an alcohol, an acid derivative and to several polar metabolites. As for other species investigated, the main pathway of meloxicam biotransformation in cat is oxidation.

Elimination
Meloxicam is eliminated with a half-life of 24 hours. The detection of metabolites from the parent compound in urine and faeces, but not in plasma is indicative for their rapid excretion. 21% of the recovered dose is eliminated in urine (2% as unchanged meloxicam, 19% as metabolites) and 79% in the faeces (49% as unchanged meloxicam, 30% as metabolites).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium benzoate
Glycerol
Citric acid monohydrate
Xanthan gum
Povidone
Sodium dihydrogen phosphate monohydrate
Simethicone emulsion
Honey flavour
Silica, colloidal anhydrous
Water, purified

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after first opening the immediate packaging:
3 ml and 5 ml bottle: 14 days
10 ml and 15 ml bottle: 6 months

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

White high density polyethylene bottle containing 10 ml or 15 ml with a tamper proof child resistant closure.

White polypropylene bottle containing 3 ml or 5 ml with a tamper proof child resistant closures.
Each bottle is packed in a cardboard box with a 1 ml measuring syringe (barrel in polypropylene and plunger/piston in high density polyethylene).
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

EU Pharmaceuticals Ltd
37 Geraldine Road
London
SW18 2NR

8. MARKETING AUTHORISATION NUMBER

Vm 39787/5012

9. DATE OF FIRST AUTHORISATION

02 February 2024

10. DATE OF REVISION OF THE TEXT

February 2024

PROHIBITION OF SALE, SUPPLY AND/OR USE

To be supplied only on veterinary prescription.

Approved 02 February 2024