# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chanoxidyl 1.5 mg/ml oral suspension for dogs

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:

**Active substance:**
Meloxicam 1.5 mg.

**Excipient:**
Sodium benzoate 5 mg.

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Oral suspension.

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Dogs.

### 4.2 Indications for use, specifying the target species

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

### 4.3 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 to the active substance or to any of the excipients.
Do not use in dogs 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 increased renal toxicity.

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.

## 4.6 Adverse reactions (frequency and seriousness)

Typical adverse reactions of NSAIDs such as loss of appetite, vomiting, diarrhoea, faecal occult blood, lethargy and renal failure have very rarely been reported. In very rare cases haemorrhagic diarrhoea, haematemesis, gastrointestinal ulceration and elevated liver enzymes have 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 adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

## 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.
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.

### 4.9 Amounts to be administered and administration route

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

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 a 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. 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. 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.
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.

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

In the case of overdosage symptomatic treatment should be initiated.

### 4.11 Withdrawal period

Not applicable.

## 5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-inflammatory and Anti-rheumatic products, Non-steroids (oxicams).
ATCvet 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
Meloxicam is completely absorbed following oral administration and maximal plasma concentrations are obtained after approximately 4.5 hours. When the product is used according to the recommended dosage regime, steady state concentrations of meloxicam in plasma are reached on the second day of treatment.

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. The volume of distribution is 0.3 l/kg.

Metabolism
Meloxicam is predominantly found in plasma and is also a major biliary excretion product whereas urine contains only traces of the parent compound. Meloxicam is metabolised to an alcohol, an acid derivative and to several polar metabolites. All major metabolites have been shown to be pharmacologically inactive.

Elimination
Meloxicam is eliminated with a half-life of 24 hours. Approximately 75% of the administered dose is eliminated via faeces and the remainder via urine.

# 6. PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Sodium Benzoate
Saccharin Sodium
Sodium Carboxyl Methyl Cellulose
Colloidal Silicon Dioxide
Citric Acid Monohydrate
Sorbitol Solution
Disodium Hydrogen-Phosphate Dodecahydrate
Honey Flavour.

## 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: 2 years.
Shelf life after first opening the immediate packaging: 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

42, 100 or 200 ml polyethylene terephthalate (PET) bottle with a tamper resistant child proof closure, and a 15 ml HDPE bottle with a tamper resistant child proof closure, and two polypropylene measuring syringes: one for small dogs (up to 20 kg) and one for bigger dogs (up to 60 kg).

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

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 39787/5001

## 9. DATE OF FIRST AUTHORISATION

05 May 2022

## 10. DATE OF REVISION OF THE TEXT

March 2023

## PROHIBITION OF SALE, SUPPLY AND/OR USE

To be supplied only on veterinary prescription.

Approved 10 March 2023