

Pyrocam[®]

Meloxicam for oral use

- ▶ 15 mg meloxicam/ml
- ▶ Oral Suspension



Pyrocam[®] Oral Suspension



Meloxicam is a widely used Non-Steroidal Anti-Inflammatory Drug (NSAID) characterised by:

High potency

- ▶ Proven efficacy against^{1,2,3}
 - Inflammation¹
 - Fever²
 - Pain³
- ▶ Low daily dosage: 0.4 mg/kg bodyweight/day

High safety margin

- ▶ Selective COX-2 inhibition⁴
- ▶ Excellent tolerance
 - In the gastro-intestinal mucosa and kidneys
 - In the blood circulation
- ▶ For sows, weaners and fatteners
- ▶ Compatible with antibiotic therapy, if required

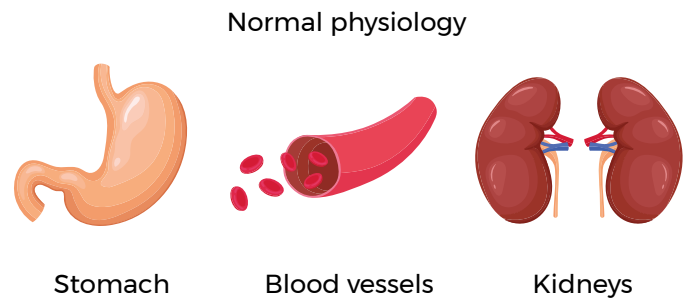
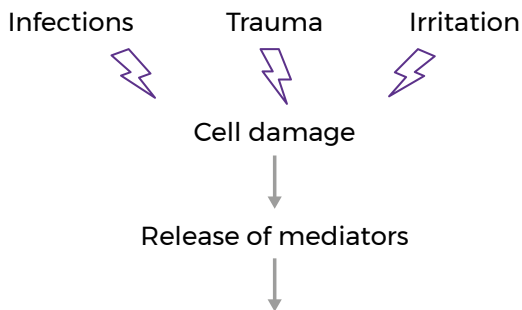
Fast clinical recovery

- ▶ Fast absorption
- ▶ High absorption rate
- ▶ Long-lasting tissue concentration⁵

High potency and safety margin

Mode of action of NSAIDs

Inhibition of cyclo-oxygenase (COX) is the common mode of action of NSAIDs. Cyclo-oxygenase induces prostaglandins production. COX-1 and COX-2 are 2 isoforms provoking different effects. NSAIDs relieve inflammation, fever and pain by inhibiting the activity of COX-2, but may also impact COX-1 to a certain extent.¹



COX-2

induction of prostaglandins provoking

Undesirable side effects:

- ▶ Inflammation
- ▶ Fever
- ▶ Pain

COX-1

induction of prostaglandins provoking

Normal physiological effects:

- ▶ Protection of the gastro-intestinal mucosa
- ▶ Blood clotting by platelet aggregation
- ▶ Protection of the kidneys

The COX inhibition pattern depends on the selected NSAID⁶

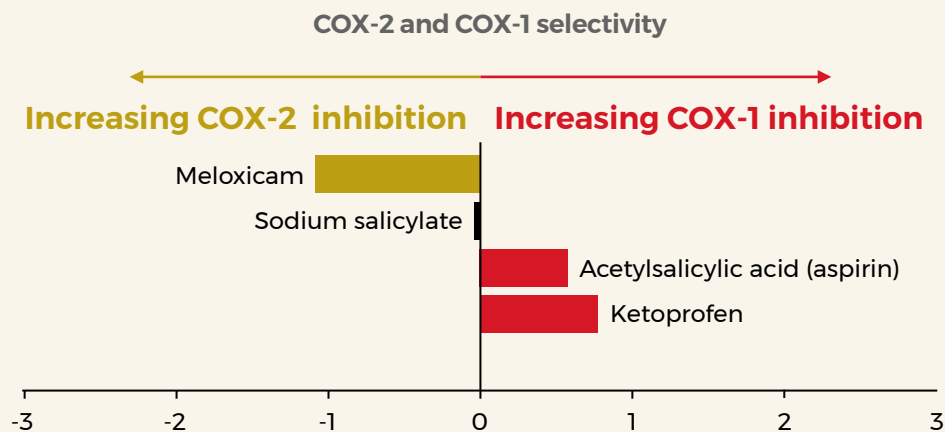


Figure 1. COX-2 and COX-1 selectivity of 4 NSAIDs for oral use in pigs. The vertical line indicates equiactivity.

Meloxicam: Selective inhibition of COX-2

- ▶ Excellent beneficial actions against
 - Inflammation
 - Fever
 - Pain
- ▶ High safety margin

Other NSAIDs: Greater inhibition of COX-1

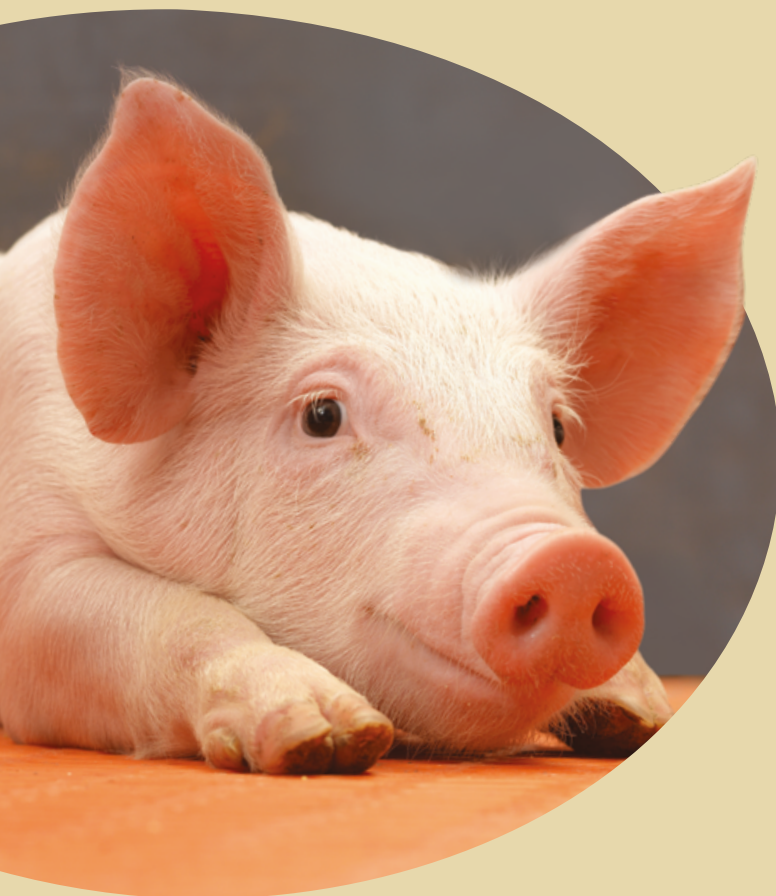
- ▶ Lower potency
- ▶ Harmful side effects
 - Ulcers and gastro-intestinal irritation
 - Delayed blood clotting
 - Renal toxicity

Pyrocam® (meloxicam) is a selective inhibitor of COX-2

Table 1. Main activities of meloxicam, other NSAIDs and paracetamol following oral use:

✓✓✓✓excellent; ✓✓✓good; ✓✓medium; ✓low; – no effect ^{2,3,4,7 to 14}

	Meloxicam	Acetylsalicylic acid (aspirin)	Sodium salicylate	Ketoprofen	Paracetamol
Anti-inflammatory effect	✓✓✓✓	✓✓	✓✓	✓✓✓✓	–
Antipyretic effect	✓✓✓	✓	✓	✓✓✓✓	✓✓
Analgesic, pain relief effect	✓✓✓✓	✓✓	✓✓	✓✓	✓✓✓✓
Gastrointestinal safety	✓✓✓✓	✓	✓✓	✓	✓✓✓
Anti-arthritic activity	✓✓✓	✓	✓	✓✓	✓✓



Contraindications

Do not use in pigs suffering from impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of ulcerogenic gastrointestinal lesions. Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Special warnings

None.

Special precautions for safe use in the target species

If adverse events occur, treatment should be discontinued and the advice of a veterinarian should be sought. Avoid use in very severely dehydrated, hypovolaemic or hypotensive pigs which require parenteral rehydration, as there may be a potential risk of renal toxicity.

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

This veterinary medicinal product may cause hypersensitivity (allergic reactions). People with known hypersensitivity to non-steroidal anti-inflammatory drugs or parabens should avoid contact with the veterinary medicinal product. This veterinary medicinal product can cause eye irritation. Personal protective equipment consisting of eye protection should be worn when handling the veterinary medicinal product. In case of contact with the eyes, immediately rinse thoroughly with water. Avoid oral exposure, including hand-to-mouth contact. Wash hands after use. Do not eat, drink or smoke while handling the veterinary medicinal product. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician. Meloxicam may have adverse effects on pregnancy and/or embryofoetal development. Avoid dermal exposure including hand-to-mouth contact. Pregnant women or women attempting to conceive should wear impermeable gloves when administering the veterinary medicinal product.

Special precautions for the protection of the environment

Not applicable.

Adverse events

None known.

Use during pregnancy and lactation

Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction

Do not administer concurrently with glucocorticosteroids, other non-steroidal anti-inflammatory drugs or with anticoagulant agents.

Special precautions for the disposal of unused veterinary medicinal products

Medicines should not be disposed of via wastewater or household waste.

Fast clinical recovery

Excellent absorption from the gastro-intestinal tract*

- ▶ Fast: Maximum plasma concentration after 2 hours



- ▶ High absorption rate: 92%

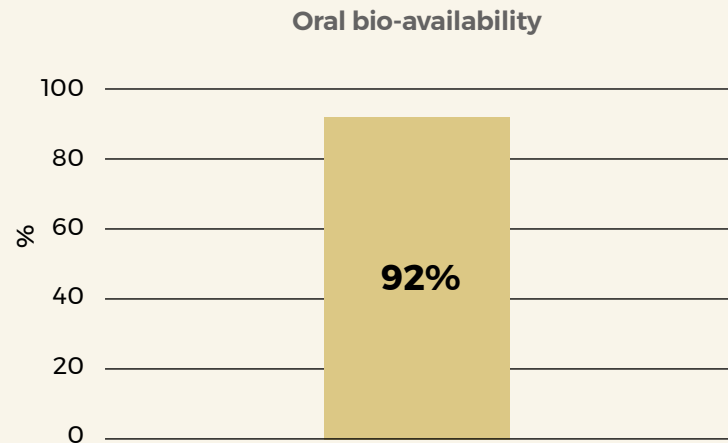


Figure 2. Bio-availability of meloxicam following oral administration in pigs

Long-lasting tissue concentration⁵

- ▶ Accumulation in inflamed tissue
- ▶ Slow tissue depletion of meloxicam

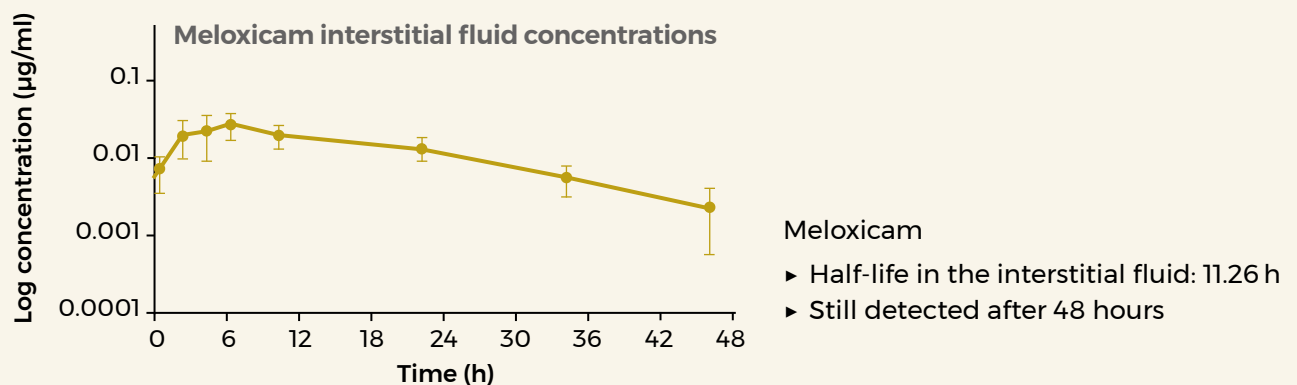


Figure 3. Meloxicam interstitial fluid concentrations following a single injection of 0.4 mg/kg bodyweight (Limit of Quantification: 0.001 µg/ml)

Pyrocam® 15 mg/ml Oral Suspension

Product specifications

- ▶ 1 ml contains 15 mg meloxicam
- ▶ Contains vanillin

Target species

Pigs

Indications for use

- ▶ Non-infectious locomotory disorders to reduce the symptoms of lameness and inflammation.
- ▶ Adjunctive therapy in the treatment of puerperal septicaemia and toxæmia (Mastitis-Metritis-Agalactia syndrome MMA) with appropriate antibiotic therapy.

Dosing

- ▶ 0.4 mg/kg bodyweight/day orally, corresponding to 2.7 ml/100 kg bodyweight/day*
- ▶ In combination with antibiotic therapy, as appropriate
- ▶ A second administration can be given after 24 hours

* The veterinary medicinal product is intended for individual treatment only. Preferably to be administered mixed with a small quantity of feed. Alternatively to be given prior to feeding, directly into the mouth. The suspension should be measured using the syringe provided in the package.

* Can be used during pregnancy and lactation.

* In cases of MMA with severely disturbed general demeanour (e.g. anorexia) the use of an injectable meloxicam product approved for the treatment of MMA is recommended.

Withdrawal period

Meat and offal: 5 days

Shelf life and storage

- ▶ Shelf life
 - as packaged for sale: 2 years
 - after first opening the immediate packaging: 1 month
- ▶ Do not freeze
- ▶ Shake before use

Overdose

The administration at a 5-fold overdose of the recommended dose for an extended period (6 days) did not induce any toxicological or pathological changes.

Packaging

- ▶ 1 l, 250 ml and 125 ml high density polyethylene bottle.
- ▶ Measuring syringe with a measuring scale from 20 to 300 kg, graduated at 20 kg intervals.
- ▶ Not all pack sizes may be marketed.



*References available upon request

*This brochure follows the authorised EU SPC

*Consult the local label

*Use medicines responsibly

*POM-V