SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Inflacam 5 mg/ml solution for injection for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Meloxicam	5 mg	
Excipients:		
Qualitative composition and other constituents		Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Ethanol (96 %)		159.8 mg
Poloxamer 188		
Macrogol 400		

A clear yellow solution.

Water for injections.

Disodium edetate

Sodium hydroxide

Each ml contains:

Active substance:

3. CLINICAL INFORMATION

Hydrochloric acid, concentrated

3.1 Target species

Dogs and cats.

Glycine

Meglumine

3.2 Indications for use for each target species

Dogs

Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders. Reduction of post-operative pain and inflammation following orthopaedic and soft tissue surgery.

Cats

Reduction of post-operative pain after ovariohysterectomy and minor soft tissue surgery.

3.3 Contraindications

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 case of hypersensitivity to the active substance or to any of the excipients.

Do not use in animals less than 6 weeks of age nor in cats of less than 2 kg. Refer to section 3.7.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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

During anaesthesia, monitoring and fluid therapy should be considered as standard practice.

Any oral follow-up therapy using meloxicam or other NSAIDs should not be administered in cats, as appropriate dosage regimens for such follow-up treatments have not been established.

<u>Special precautions to be taken by the person administering the veterinary medicinal product to animals:</u>

Accidental self-injection may give rise to pain.

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

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

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs and cats:

Very rare	Appetite loss, Lethargy
(<1 animal / 10,000 animals treated, including isolated reports):	Vomiting, Diarrhoea, Blood in faeces ¹ , Haemorrhagic diarrhoea ² , Haematemesis ² , Gastric ulcer ² , Small intestine ulcer ² , Large intestine ulcer ²
	Elevated liver enzymes
	Renal failure
	Anaphylactoid reaction ³

¹Occult

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 its local representative or the national competent authority via the national reporting system. See also the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Do not use in pregnant or lactating animals.

3.8 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. The veterinary medicinal product must not be administered in conjunction with other NSAIDs or glucocorticosteroids. Concurrent administration of potential nephrotoxic drugs should be avoided. In animals at anaesthetic risk (e.g. aged animals) intravenous or subcutaneous fluid therapy during anaesthesia should be taken into consideration. When anaesthesia and NSAID are concomitantly administered, a risk for renal function cannot be excluded.

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.

²These 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.

³If such reaction occurs, it should be treated symptomatically.

The treatment-free period should however take into account the pharmacological properties of the veterinary medicinal products previously used.

3.9 Administration routes and dosage

Subcutaneous or intravenous use (dogs). Subcutaneous use (cats).

Dogs

Musculo-skeletal disorders:

Single subcutaneous injection at a dosage of 0.2 mg meloxicam/kg body weight (i.e. 0.4 ml/10 kg body weight).

Inflacam 1.5 mg/ml oral suspension for dogs or Inflacam 1 mg and 2.5 mg chewable tablets for dogs may be used for continuation of treatment at a dosage of 0.1 mg meloxicam/kg body weight, 24 hours after administration of the injection.

Reduction of post-operative pain (over a period of 24 hours):

Single intravenous or subcutaneous injection at a dosage of 0.2 mg meloxicam/kg body weight (i.e. 0.4 ml/10 kg body weight) before surgery, for example at the time of induction of anaesthesia.

Cats

Reduction of post-operative pain:

Single subcutaneous injection at a dosage of 0.3 mg meloxicam/kg body weight (i.e. 0.06 ml/kg body weight) before surgery, for example at the time of induction of anaesthesia.

To ensure a correct dosage, body weight should be determined as accurately as possible.

The use of suitably calibrated measuring equipment is recommended.

Avoid introduction of contamination during use.

Maximum number of piercings is 42 for all presentations.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

In case of overdose, symptomatic treatment should be initiated.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AC06.

4.2 Pharmacodynamics

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).

4.3 Pharmacokinetics

Absorption

Following subcutaneous administration, meloxicam is completely bioavailable and maximal mean plasma concentrations of 0.73 mcg/ml in dogs and 1.1 mcg/ml in cats were reached approximately 2.5 hours and 1.5 hours post administration, respectively.

Distribution

There is a linear relationship between the dose administered and plasma concentration observed in the therapeutic dose range in dogs. More than 97 % of meloxicam is bound to plasma proteins. The volume of distribution is 0.3 l/kg in dogs and 0.09 l/kg in cats.

Metabolism

In dogs, 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.

In cats, 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

In dogs, 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.

In cats, 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).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years. Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Keep the vial in the outer carton.

5.4 Nature and composition of immediate packaging

Cardboard box containing one 10 ml, 20 ml or 100 ml clear type I glass injection vial. Each vial is closed with a type I bromobutyl rubber stopper and sealed with an aluminium cap.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd

7. MARKETING AUTHORISATION NUMBER

Vm 08749/5015

8. DATE OF FIRST AUTHORISATION

16/08/2012

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

September 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall

Approved: 11 December 2025