ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rheumocam 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 case 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

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. This product for dogs should not be used in cats as it is not suitable for use in this species. In cats, Rheumocam 0.5 mg/ml oral suspension for cats should be used.

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

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 occasionally 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.

If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

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).

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. Rheumocam 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 food.
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.
Particular care should be taken with regard to the accuracy of dosing.
The suspension can be given using the Rheumocam 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(s)

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 7.5 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

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

Honey Flavour.

6.2 Major incompatibilities

None known.

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

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway,
Ireland.

8. MARKETING AUTHORISATION NUMBERS

42 ml: EU/2/07/078/001
100 ml: EU/2/07/078/002
200 ml: EU/2/07/078/003
15 ml: EU/2/07/078/004

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10/01/2008.
Date of last renewal: 18/12/2012.

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rheumocam 1 mg chewable tablets for dogs
Rheumocam 2.5 mg chewable tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One chewable tablet contains:

Active substance:
Meloxicam 1 mg
Meloxicam 2.5 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Chewable tablets.
Pale-yellow, single-scored, chewable tablets.

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 dogs less than 6 weeks of age or less than 4 kg body weight.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings

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.

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

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 occasionally 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.

If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

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).

4.7 Use during pregnancy, lactation or lay

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

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. Rheumocam 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 medicines should be observed for at least 24 hours before commencement of treatment. The treatment-free period, however, should take into account the pharmacokinetic properties of the products used previously.

4.9 Amounts to be administered and administration route

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.
Each chewable tablet contains either 1 mg or 2.5 mg meloxicam, which corresponds to the daily maintenance dose for a 10 kg body weight dog, or a 25 kg body weight dog respectively. Each chewable tablet can be halved for accurate dosing according to the individual body weight of the animal. Rheumocam chewable tablets can be administered with or without food, are flavoured and are taken by most dogs voluntarily.

Dose scheme for the maintenance dose:

Body weight (kg)	Number of chewable tablets		mg/kg
	1 mg	2.5 mg	
4.0–7.0	½		0.13–0.1
7.1–10.0	1		0.14–0.1
10.1–15.0	1½		0.15–0.1
15.1–20.0	2		0.13–0.1
20.1–25.0		1	0.12–0.1
25.1–35.0		1½	0.15–0.1
35.1–50.0		2	0.14–0.1

The use of Rheumocam oral suspension for dogs may be considered for an even more precise dosing. For dogs weighing less than 4 kg the use of Rheumocam oral suspension for dogs is recommended.

A clinical response is normally seen within 3–4 days. Treatment should be discontinued after 10 days if no clinical improvement is apparent.

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

In case of overdosage symptomatic treatment should be initiated.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-inflammatory and Anti-rheumatic products, non-steroids (oxicams). ATCvet code: QMO1AC06.

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-l (COX-I).

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

Lactose monohydrate
Silicified microcrystalline cellulose
Sodium acid citrate
Crospovidone
Talc
Pork Flavour
Magnesium stearate.

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.

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

Rheumocam chewable tablets are supplied in:
PVC/PVDC (250. 60) blister packs with a 20 micron foil.
Pack sizes: 20 and 100 tablets.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway,
Ireland

8. MARKETING AUTHORISATION NUMBERS

EU/2/07/078/005
EU/2/07/078/006
EU/2/07/078/007

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10/01/2008.
Date of last renewal: 18/12/2012.

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rheumocam 15 mg/ml oral suspension for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:

Active substance:
Meloxicam 15 mg

Excipient:
Sodium benzoate 5 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension.
Honey flavoured, white to off-white viscous oral suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Horses

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

Do not use in pregnant or lactating mares.
Do not use in horses 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 horses less than 6 weeks of age.

4.4 Special warnings

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.

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

4.6 Adverse reactions (frequency and seriousness)

Isolated cases of adverse reactions typically associated with NSAIDs were observed in clinical trials (slight urticaria, diarrhoea). Symptoms were reversible. In very rare cases loss of appetite, lethargy abdominal pain and colitis have been reported. In very rare cases anaphylactoid reactions, which may be serious (including fatal), may occur and should be treated symptomatically.

If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

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).

4.7 Use during pregnancy, lactation or lay

Laboratory studies in cattle have not provided any evidence for teratogenic, foetotoxic, or maternotoxic effects. However, no data have been generated in horses. Therefore the use in this species is not recommended during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

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

4.9 Amounts to be administered and administration route

To be administered either mixed with food or directly into the mouth at a dosage of 0.6 mg/kg body weight, once daily, up to 14 days. In case the product is mixed with food, it should be added to a small quantity of food, prior to feeding.

The suspension should be given using the Rheumocam measuring syringe provided in the package. The syringe fits onto the bottle and has a 2 ml scale.

Shake well before use.

Avoid introduction of contamination during use.

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

In the case of overdose symptomatic treatment should be initiated.

4.11 Withdrawal period(s)

Meat and offal: 3 days.
Not authorised for use in lactating animals producing milk for human consumption.

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. Meloxicam also has anti-endotoxic properties because it has been shown to inhibit production of thromboxane B_2 induced by intravenous *E. coli* endotoxin administration in calves and pigs.

5.2 Pharmacokinetic particulars

Absorption
When the product is used according to the recommended dosage regime, the oral bioavailability is approximately 98%. Maximal plasma concentrations are obtained after approximately 2–3 hours. The accumulation factor of 1.08 suggests that meloxicam does not accumulate when administered daily.

Distribution
Approximately 98% of meloxicam is bound to plasma proteins. The volume of distribution is 0.12 l/kg.

Metabolism
The metabolism is qualitatively similar in rats, mini-pigs, humans, cattle and pigs, although quantitatively there are differences. The major metabolites found in all species were the 5-hydroxy- and 5-carboxy- metabolites and the oxalyl- metabolite. The metabolism in horses was not investigated. All major metabolites have been shown to be pharmacologically inactive.

Elimination
Meloxicam is eliminated with a terminal half-life of 7.7 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Saccharin sodium
Carmellose sodium
Silica, colloidal anhydrous
Citric acid monohydrate
Sorbitol, liquid (non-crystallising)
Disodium phosphate dodecahydrate
Sodium benzoate
Honey aroma
Purified water

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening of the immediate packaging: 3 months.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.
After administration of the veterinary medicinal product, close the bottle by replacing the cap, wash the measuring syringe with warm water and let it dry.

6.5 Nature and composition of immediate packaging

HDPE bottle containing 100 or 250 ml with a tamper proof child resistant closure and a polypropylene measuring syringe.

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

Chanelle Pharmaceuticals Manufacturing Limited
Loughrea,
Co. Galway,
Ireland.

8. MARKETING AUTHORISATION NUMBERS

EU/2/07/078/009 100 ml
EU/2/07/078/010 250 ml

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10/01/2008.
Date of last renewal: 18/12/2012.

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rheumocam 20 mg/ml solution for injection for cattle, pigs and horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:

Active substance:
Meloxicam 20 mg

Excipient:
Ethanol (96 percent): 159.8 mg.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, pigs and horses.

4.2 Indications for use, specifying the target species

Cattle:

For use in acute respiratory infection with appropriate antibiotic therapy to reduce clinical signs in cattle.
For use in diarrhoea in combination with oral re-hydration therapy to reduce clinical signs in calves of over one week of age and young, non-lactating cattle.
For adjunctive therapy in the treatment of acute mastitis, in combination with antibiotic therapy.

Pigs:

For use in non-infectious locomotor disorders to reduce the symptoms of lameness and inflammation.
For adjunctive therapy in the treatment of puerperal septicaemia and toxaemia (mastitis-metritis-agalactia syndrome) with appropriate antibiotic therapy.

Horses:

For use in the alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders.
For the relief of pain associated with equine colic.

4.3 Contraindications

See also section 4.7.
Do not use in horses less than 6 weeks of age.

Do not use in animals suffering from impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of ulcerogenic gastrointestinal lesions.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
For the treatment of diarrhoea in cattle, do not use in animals of less than one week of age.

4.4 Special warnings

None.

4.5 Special precautions for use

Special precautions for use in animals

If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.
Avoid use in very severely dehydrated, hypovolaemic or hypotensive animals which require parenteral rehydration, as there may be a potential risk of renal toxicity.
In case of inadequate relief of pain when used in the treatment of equine colic, careful re-evaluation of the diagnosis should be made as this could indicate the need for surgical intervention.

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

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.

4.6 Adverse reactions (frequency and seriousness)

In cattle and pigs, subcutaneous, intramuscular as well as intravenous administration is well tolerated; only a slight transient swelling at the injection site following subcutaneous administration was observed in less than 10 % of the cattle treated in clinical studies.
In horses, a transient swelling at the injection site can occur but resolves without intervention.
In very rare cases anaphylactoid reactions, which may be serious (including fatal), may occur and should be treated symptomatically.

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).

4.7 Use during pregnancy, lactation or lay

Cattle and pigs:

Can be used during pregnancy and lactation.

Horses:

Do not use in pregnant or lactating mares.
See also section 4.3.

4.8 Interaction with other medicinal products and other forms of interaction

Do not administer concurrently with glucocorticosteroids, other NSAIDs or with anti-coagulant agents.

4.9 Amounts to be administered and administration route

Maximum number of piercings is 14 for the 20 ml, 50 ml and 100 ml stoppers and 20 for the 250 ml stopper.

Cattle:

Single subcutaneous or intravenous injection at a dosage of 0.5 mg meloxicam/kg body weight (i.e. 2.5 ml/100 kg body weight) in combination with antibiotic therapy or with oral re-hydration therapy, as appropriate.

Pigs:

Single intramuscular injection at a dosage of 0.4 mg meloxicam/kg body weight (i.e. 2.0 ml/100 kg body weight) in combination with antibiotic therapy, as appropriate. If required, a second administration of meloxicam can be given after 24 hours.

Horses:

Single intravenous injection at a dosage of 0.6 mg meloxicam/kg body weight (i.e. 3.0 ml/100 kg body weight).
For use in the alleviation of inflammation and the relief of pain in both acute and chronic musculo–skeletal disorders, Rheumocam 15 mg/ml oral suspension may be used for continuation of treatment at a dosage of 0.6 mg meloxicam/kg body weight, 24 hours after administration of the injection.

Avoid introduction of contamination during use.

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

In the case of overdose, symptomatic treatment should be initiated.

4.11 Withdrawal period(s)

Cattle:

Meat and offal: 15 days.
Milk: 5 days.

Pigs:

Meat and offal: 5 days

Horses:

Meat and offal: 5 days.
Not authorised for use in horses producing milk for human consumption.

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, anti-exudative, analgesic and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it also inhibits collagen-induced thrombocyte aggregation. Meloxicam also has anti-endotoxic properties because it has been shown to inhibit production of thromboxane B2 induced by *E. coli* endotoxin administration in calves, lactating cows and pigs.

5.2 Pharmacokinetic particulars

Absorption
After a single subcutaneous dose of 0.5 mg meloxicam/kg, C_{max} values of 2.1 µg/ml and 2.7 µg/ml were reached after 7.7 hours and 4 hours in young cattle and lactating cows, respectively.
After two intramuscular doses of 0.4 mg meloxicam/kg, a C_{max} value of 1.9 µg/ml was reached after 1 hour in pigs.

Distribution
More than 98 % of meloxicam is bound to plasma proteins. The highest meloxicam concentrations are to be found in liver and kidney. Comparatively low concentrations are detectable in skeletal muscle and fat.

Metabolism
Meloxicam is predominantly found in plasma. In cattle, meloxicam is also a major excretion product in milk and bile whereas urine contains only traces of the parent compound. In pigs, bile and urine contain 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. The metabolism in horses has not been investigated.

Elimination
Meloxicam is eliminated with a half-life of 26 hours and 17.5 hours after subcutaneous injection in young cattle and lactating cows, respectively.
In pigs, after intramuscular administration the mean plasma elimination half-life is approximately 2.5 hours.
In horses, after intravenous injection meloxicam is eliminated with a terminal half-life of 8.5 hours.
Approximately 50 % of the administered dose is eliminated via urine and the remainder via faeces.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Ethanol (96%)
- Poloxamer 188
- Macrogol 400
- Glycine
- Sodium hydroxide
- Hydrochloric acid, concentrated
- Meglumine
- Water for injections.

6.2 Major incompatibilities

None known.

6.3 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.

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

Cardboard box with 1 colourless glass injection vial containing 20 ml, 50 ml, 100 ml or 250 ml. Each vial is closed with a rubber stopper and sealed with an aluminium cap.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway,
Ireland.

8. MARKETING AUTHORISATION NUMBERS

EU/2/07/078/011 20 ml
EU/2/07/078/012 50 ml
EU/2/07/078/013 100 ml
EU/2/07/078/014 250 ml

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10/01/2008.
Date of last renewal: 18/12/2012.

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:

Active substance:
Meloxicam 5 mg

Excipient(s):
Ethanol (96%) 159.8 mg.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats.

4.2 Indications for use, specifying the 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.

4.3 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 4.7.

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.

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.

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

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.

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 occasionally been reported. In very rare cases elevated liver enzymes have been reported.

In very rare cases, haemorrhagic diarrhoea, haematemesis, and gastrointestinal ulceration 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.

In very rare cases anaphylactoid reactions may occur and should be treated symptomatically.

If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

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).

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.
Do not use in pregnant or lactating animals.

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. Rheumocam 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. 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

Maximum number of piercings is 42 for all presentations.

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).

Rheumocam 1.5 mg/ml oral suspension for dogs or Rheumocam 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.

Particular care should be taken with regard to the accuracy of dosing.

Avoid introduction of contamination during use.

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

In the case of overdose symptomatic treatment should be initiated.

4.11 Withdrawal period(s)

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
Following subcutaneous administration, meloxicam is completely bioavailable and maximal mean plasma concentrations of 0.73 µg/ml in dogs and 1.1 µg/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).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol (96%)
Poloxamer 188
Macrogol 400
Glycine
Disodium edetate
Sodium hydroxide
Hydrochloric acid, concentrated
Meglumine
Water for injections.

6.2 Major incompatibilities

None known.

6.3 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.

6.4 Special precautions for storage

Keep the vial in the outer carton.

6.5 Nature and composition of immediate packaging

Carton box containing one colourless glass injection vial of 10 ml, 20 ml or 100ml, closed with a bromobutyl rubber stopper and sealed with an aluminium cap.

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Limited
Loughrea,
Co. Galway,
Ireland.

8. MARKETING AUTHORISATION NUMBERS

EU/2/07/078/015 10 ml
EU/2/07/078/016 20 ml
EU/2/07/078/017 100 ml

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10/01/2008.
Date of last renewal: 18/12/2012.

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rheumocam 5 mg/ml solution for injection for cattle and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:

Active substance:
Meloxicam 5 mg

Excipient:
Ethanol (96%) 159.8 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection
Clear yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (calves and young cattle) and pigs

4.2 Indications for use, specifying the target species

Cattle:

For use in acute respiratory infection with appropriate antibiotic therapy to reduce clinical signs in cattle.
For use in diarrhoea in combination with oral re-hydration therapy to reduce clinical signs in calves of over one week of age and young, non-lactating cattle.

Pigs:

For use in non-infectious locomotor disorders to reduce the symptoms of lameness and inflammation.
For the relief of post operative pain associated with minor soft tissue such as castration.

4.3 Contraindications

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

For the treatment of diarrhoea in cattle, do not use in animals of less than one week of age.
Do not use in pigs less than 2 days old.

4.4 Special warnings for each target species

Treatment of piglets with Rheumocam before castration reduces post operative pain. To obtain pain relief during surgery co-medication with an appropriate anaesthetic/sedative is needed.

To obtain the best possible pain relieving post surgery Rheumocam should be administered 30 minutes before surgical intervention.

4.5 Special precautions for use

Special precautions for use in animals

If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.
Avoid use in very severely dehydrated, hypovolaemic or hypotensive animals 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

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.

4.6 Adverse reactions (frequency and seriousness)

Subcutaneous, intramuscular as well as intravenous administration is well tolerated; only a slight transient swelling at the injection site following subcutaneous administration was observed in less than 10 % of the cattle treated in clinical studies.

In very rare cases anaphylactoid reactions which may be serious (including fatal) may occur and should be treated symptomatically.

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).

4.7 Use during pregnancy, lactation or lay

Cattle: Can be used during pregnancy.
Pigs: Can be used during pregnancy and lactation

4.8 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.

4.9 Amounts to be administered and administration route

Cattle:

Single subcutaneous or intravenous injection at a dosage of 0.5 mg meloxicam/kg body weight (i.e. 10 ml/100 kg body weight) in combination with antibiotic therapy or with oral re-hydration therapy, as appropriate.

Pigs:

Locomotor disorders:
Single intramuscular injection at a dosage of 0.4 mg meloxicam/kg body weight (i.e. 2.0 ml/25 kg body weight). If required, a second administration of meloxicam can be given after 24 hours.

Reduction of post-operative pain
Single intramuscular injection at a dosage of 0.4 mg meloxicam/kg body weight (i.e. 0.4 ml/5 kg body weight) before surgery.

Particular care should be taken with regard to the accuracy of dosing including the use of an appropriate dosing device and careful estimation of body weight.
Avoid introduction of contamination during use.

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

In the case of overdose symptomatic treatment should be initiated.

4.11 Withdrawal period(s)

Cattle: Meat and offal: 15 days

Pigs: Meat and offal: 5 days

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, anti-exudative, analgesic and antipyretic effects. Meloxicam also has anti-endotoxic properties because it has been shown to inhibit production of thromboxane B2 induced by *E. coli* endotoxin administration in calves and pigs.

5.2 Pharmacokinetic particulars

Absorption
After a single subcutaneous dose of 0.5 mg meloxicam/kg, C_{max} values of 2.1 µg/ml were reached after 7.7 hours in young cattle.
Following single intramuscular doses of 0.4 mg meloxicam/kg, a C_{max} value of 1.1 to 1.5 µg/ml was reached within 1 hour in pigs.

Distribution
More than 98 % of meloxicam is bound to plasma proteins. The highest meloxicam concentrations are to be found in liver and kidney. Comparatively low concentrations are detectable in skeletal muscle and fat.

Metabolism
Meloxicam is predominantly found in plasma. In cattle, meloxicam is also a major excretion product in milk and bile whereas urine contains only traces of the parent compound. In pigs, bile and urine contain 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 26 hours after subcutaneous injection in young cattle.

In pigs, after intramuscular administration the mean plasma elimination half-life is approximately 2.5 hours.

Approximately 50 % of the administered dose is eliminated via urine and the remainder via faeces.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Ethanol (96%)
- Poloxamer 188
- Macrogol 400
- Glycine
- Disodium edetate
- Sodium hydroxide
- Hydrochloric acid, concentrated
- Meglumine
- Water for injections

6.2 Major incompatibilities

None known

6.3 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

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

Carton box containing 1 colourless glass injection vial of 20 ml, 50 ml or 100 ml, closed with a bromobutyl rubber stopper and sealed with an aluminium cap.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway,
Ireland.

8. MARKETING AUTHORISATION NUMBERS

EU/2/07/078/018 20 ml
EU/2/07/078/019 50 ml
EU/2/07/078/020 100 ml

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10/01/2008.
Date of last renewal: 18/12/2012.

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rheumocam 330 mg, granules for horses.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One sachet contains:

Active substance:
Meloxicam 330 mg.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Granules in sachet.
Pale yellow granules.

4. CLINICAL PARTICULARS

4.1 Target species

Horses.

4.2 Indications for use, specifying the target species

Alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders in horses weighing between 500 and 600 kg.

4.3 Contraindications

Do not use in pregnant or lactating mares.
Do not use in horses 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 horses 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.
In order to minimise risk of intolerance, the product should be mixed into muesli feed.
This product is only for use in horses weighing between 500 and 600 kg.

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.

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

4.6 Adverse reactions (frequency and seriousness)

Isolated cases of adverse reactions typically associated with NSAIDs were observed in clinical trials (slight urticaria, diarrhoea). Symptoms were reversible. In very rare cases loss of appetite, lethargy, abdominal pain and colitis have been reported. In very rare cases anaphylactoid reactions, which may be serious (including fatal), may occur and should be treated symptomatically.

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).

4.7 Use during pregnancy, lactation or lay

Laboratory studies in cattle have not provided any evidence for teratogenic, foetotoxic, or maternotoxic effects. However, no data have been generated in horses. Therefore the use in horses is not recommended during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Do not administer concurrently with glucocorticoids, other NSAIDs or with anti-coagulant agents.

4.9 Amounts to be administered and administration route

In-feed use.

To be administered mixed with food at a dose of 0.6 mg/kg body weight, once daily, up to 14 days. The product should be added to 250 g of muesli feed, prior to feeding.

Each sachet contains one dose for a horse weighing between 500 and 600 kg and the dose must not be divided into smaller doses.

Avoid introduction of contamination during use.

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

In the case of overdose symptomatic treatment should be initiated.

4.11 Withdrawal period(s)

Meat and offal: 3 days.
Not authorised for use in lactating animals producing milk for human consumption.

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. Meloxicam also has anti-endotoxic properties because it has been shown to inhibit production of thromboxane B_2 induced by intravenous *E. coli* endotoxin administration in calves and pigs.

5.2 Pharmacokinetic particulars

Absorption
When the product is used according to the recommended dosage regime, the oral bioavailability is approximately 98%. Maximal plasma concentrations are obtained after approximately 2–3 hours. The accumulation factor of 1.08 suggests that meloxicam does not accumulate when administered daily.

Distribution
Approximately 98% of meloxicam is bound to plasma proteins. The volume of distribution is 0.12 l/kg.

Metabolism
The metabolism is qualitatively similar in rats, humans, cattle and pigs (including mini-pigs), although quantitatively there are differences. The major metabolites found in all species were the 5-hydroxy- and 5-carboxy- metabolites and the oxalyl- metabolite. The metabolism in horses was not investigated. All major metabolites have been shown to be pharmacologically inactive.

Elimination
Meloxicam is eliminated with a terminal half-life of 7.7 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glucose monohydrate
Povidone
Apple flavour (containing butylated hydroxyanisole (E320))
Crospovidone

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 incorporation into muesli feed: use immediately.

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

Paper foil sachets (paper/PE/alu/PE) containing 1.5 g granules per sachet in a cardboard box with 100, 10 sachets.
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

Chanelle Pharmaceuticals Manufacturing Limited
Loughrea,
Co. Galway,
IRELAND.

8. MARKETING AUTHORISATION NUMBERS

EU/2/07/078/021
EU/2/07/078/026

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10/01/2008.
Date of last renewal: 18/12/2012.

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rheumocam 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 case 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 pain and inflammation following surgical procedures:
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.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

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 occasionally been reported. Gastrointestinal ulceration and elevated liver enzymes were reported in very rare cases.

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.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- 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).

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

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.
Post-operative pain and inflammation following surgical procedures:
After initial treatment with Rheumocam 5 mg/ml solution for injection for cats, continue treatment 24 hours later with Rheumocam 0.5 mg/ml oral suspension for cats at a dosage of 0.05 mg meloxicam/kg body weight. 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 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 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 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. 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:
The syringe fits onto the drop dispenser of the bottle and has a kg-body weight scale which corresponds to the dose of 0.05 mg meloxicam/kg bodyweight. Thus for initiation of the treatment of chronic musculo-skeletal disorders on the first day, twice the maintenance volume will be required. For initiation of the treatment of acute musculo-skeletal disorders on the first day, 4 times the maintenance volume will be required.

Shake well before use. 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.
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: Antiinflammatory and antirheumatic 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
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
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 products.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 30 months
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.
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 products 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

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea, Co. Galway, Ireland.

8. MARKETING AUTHORISATION NUMBERS

EU/2/07/078/022	10 ml
EU/2/07/078/023	15 ml
EU/2/07/078/024	3 ml
EU/2/07/078/025	5 ml

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10/01/2008
Date of last renewal: 18/12/2012

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY OR USE

C. STATEMENT OF THE MRLs

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway,
IRELAND

For Rheumocam 20 mg/ml solution for injection for cattle, pigs and horses and Rheumocam 5 mg/ml solution for injection for cats and dogs and Rheumocam 5 mg/ml solution for injection for cattle and pigs only:

Eurovet Animal Health B.V.
Handelsweg 25,
5531 AE Bladel,
The NETHERLANDS

and

Labiana Life Sciences, S.A., C/ Venus, 26, Pol. Ind. Can Parellada, Tarrasa, 08228 Barcelona

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY OR USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

The active substance in Rheumocam is an allowed substance as described in table 1 of the annex to Commission Regulation (EU) 37/2010:

Pharmacolo-gically active substance	Marker residue	Animal species	MRL	Target tissues	Other provisions	Therapeutic classification
Meloxicam	Meloxicam	Bovine, caprine, porcine, rabbit, *Equidae*	20 µg/kg 65 µg/kg 65 µg/kg	Muscle Liver Kidney	NO ENTRY	Anti-inflammatory agents/Nonsteroidal anti-inflammatory agents
		Bovine, caprine	15 µg/kg	Milk		

The excipients listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or are considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this product.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Carton for 15 ml, 42 ml, 100 ml or 200 ml bottle}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rheumocam 1.5 mg/ml oral suspension for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: 1.5 mg of meloxicam,
5 mg of sodium benzoate.

3. PHARMACEUTICAL FORM

Oral suspension.

4. PACKAGE SIZE

15 ml
42 ml
100 ml
200 ml

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.
To be administered mixed with food.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in pregnant or lactating animals.

10. EXPIRY DATE

EXP {month/year}
Once opened use within 6 months.

11. SPECIAL STORAGE CONDITIONS

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway,
Ireland.

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/07/078/004 15 ml
EU/2/07/078/001 42 ml
EU/2/07/078/002 100 ml
EU/2/07/078/003 200 ml

17. MANUFACTURER'S BATCH NUMBER

BN{number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{Label for 100 ml and 200 ml bottles}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rheumocam 1.5 mg/ml oral suspension for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: 1.5 mg of meloxicam,
5 mg of sodium benzoate.

3. PHARMACEUTICAL FORM

Oral suspension.

4. PACKAGE SIZE

100 ml
200 ml

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.
Avoid introduction of contamination during use.
To be administered mixed with food.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in pregnant or lactating animals.

10. EXPIRY DATE

EXP {month/year}
Once opened use within 6 months.

11. SPECIAL STORAGE CONDITIONS

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway,
Ireland.

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/07/078/002 100 ml
EU/2/07/078/003 200 ml

17. MANUFACTURER'S BATCH NUMBER

BN{number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Label for 15 ml and 42 ml bottle}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rheumocam 1.5 mg/ml oral suspension for dogs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 1.5 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

15 ml
42 ml

4. ROUTE(S) OF ADMINISTRATION

Shake well before use.
To be administered mixed with food.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

BN {number}

7. EXPIRY DATE

EXP {month/year}
Once opened use within 6 months.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rheumocam 1 mg chewable tablets for dogs
Rheumocam 2.5 mg chewable tablets for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Each chewable tablet contains:
Active substance:
Meloxicam 1 mg
Meloxicam 2.5 mg

3. PHARMACEUTICAL FORM

Chewable tablet

4. PACKAGE SIZE

20 tablets
100 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway,
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/07/078/005 (1 mg, 20 tablets)
EU/2/07/078/006 (1 mg, 100 tablets)
EU/2/07/078/007 (2.5 mg, 20 tablets)
EU/2/07/078/008 (2.5 mg, 100 tablets)

17. MANUFACTURER'S BATCH NUMBER

BN

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rheumocam 1 mg chewable tablets for dogs
Rheumocam 2.5 mg chewable tablets for dogs

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

BN

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Carton for 100 ml or 250 ml bottle}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rheumocam 15 mg/ml oral suspension for horses
Meloxicam

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: 15 mg of meloxicam,
5 mg of sodium benzoate.

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Horses.

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.
To be administered either mixed with a small quantity of food, prior to feeding, or directly into the mouth.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Meat and offal: 3 days.
Not authorised for use in lactating animals producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in pregnant or lactating mares.

10. EXPIRY DATE

EXP {month/year}
Once opened use within 3 months.

11. SPECIAL STORAGE CONDITIONS

After administration of the veterinary medicinal product, close the bottle by replacing the cap, wash the measuring syringe with warm water and let it dry.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway,
Ireland.

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/07/078/009 100 ml
EU/2/07/078/010 250 ml

17. MANUFACTURER'S BATCH NUMBER

BN{number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{Label for 100 ml and 250 ml bottles}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rheumocam 15 mg/ml oral suspension for horses
Meloxicam

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: 15 mg of meloxicam,
5 mg of sodium benzoate.

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Horses.

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.
Avoid introduction of contamination during use.
To be administered either mixed with a small quantity of food, prior to feeding, or directly into the mouth.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Meat and offal: 3 days.
Not authorised for use in lactating animals producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in pregnant or lactating mares.

10. EXPIRY DATE

EXP {month/year}
Once opened use within 3 months.

11. SPECIAL STORAGE CONDITIONS

After administration of the veterinary medicinal product, close the bottle by replacing the cap, wash the measuring syringe with warm water and let it dry.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway,
Ireland.

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/07/078/009 100 ml
EU/2/07/078/010 250 ml

17. MANUFACTURER'S BATCH NUMBER

BN{number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Carton for 20 ml, 50 ml, 100 ml and 250 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rheumocam 20 mg/ml solution for injection for cattle, pigs and horses
Meloxicam

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 20 mg/ml,
Ethanol (96 percent) 159.8 mg/ml.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

20 ml
50 ml
100 ml
250 ml

5. TARGET SPECIES

Cattle, pigs and horses

6. INDICATIONS

Cattle:

Acute respiratory infection.
Diarrhoea in calves of over one week of age and young, non-lactating cattle.
Acute mastitis.

Pigs:

Non-infectious locomotor disorders.
Puerperal septicaemia and toxaemia (MMA syndrome) with antibiotic therapy.

Horses:

Acute and chronic musculo-skeletal disorders.
Pain associated with equine colic.

7. METHOD AND ROUTES OF ADMINISTRATION

Cattle:

Single subcutaneous or intravenous injection.

Pigs:

Single intramuscular injection. If required, a second administration can be given after 24 hours.

Horses:

Single intravenous injection.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period:
Cattle: meat and offal: 15 days; milk: 5 days.
Pigs: meat and offal: 5 days.
Horses: meat and offal: 5 days.
Not authorised for use in horses producing milk for human consumption

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the immediate packaging: 28 days.
Once broached, use by…

11. SPECIAL STORAGE CONDITIONS

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF USED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OF RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only-to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co. Galway
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/07/078/011 20 ml
EU/2/07/078/012 50 ml
EU/2/07/078/013 100 ml
EU/2/07/078/014 250 ml

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{Label for 50 ml, 100 ml and 250 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rheumocam 20 mg/ml solution for injection for cattle, pigs and horses
Meloxicam

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 20 mg/ml,
Ethanol (96 percent) 159.8 mg/ml.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml
100 ml
250 ml

5. TARGET SPECIES

Cattle, pigs and horses

6. INDICATIONS

Read package leaflet before use.

7. METHOD AND ROUTES OF ADMINISTRATION

Cattle:

SC or IV injection.

Pigs:

IM injection.

Horses:

IV injection.

8. WITHDRAWAL PERIOD(S)

Withdrawal period:
Cattle: meat and offal: 15 days; milk: 5 days.
Pigs: meat and offal: 5 days.
Horses: meat and offal: 5 days.
Not authorised for use in horses producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the immediate packaging: 28 days.
Once broached, use by…

11. SPECIAL STORAGE CONDITIONS

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF USUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use

13. THE WORDS 'FOR ANIMAL TREATMENT ONLY' AND CONDITIONS OF RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co. Galway
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/07/078/012 50 ml
EU/2/07/078/013 100 ml
EU/2/07/078/014 250 ml

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Label for 20 ml bottles}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rheumocam 20 mg/ml solution for injection for cattle, pigs and horses
Meloxicam

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 20 mg/ml,
Ethanol (96 percent) 159.8 mg/ml.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

20 ml

4. ROUTES OF ADMINISTRATION

Cattle:

SC or IV injection.

Pigs:

IM injection.

Horses:

IV injection.

5. WITHDRAWAL PERIOD(S)

Withdrawal period:
Cattle: meat and offal: 15 days; milk: 5 days.
Pigs: meat and offal: 5 days.
Horses: meat and offal: 5 days.

Not authorised for use in horses producing milk for human consumption.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

Shelf life after first opening the immediate packaging: 28 days.
Once broached use by …

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Carton for 10 ml, 20 ml and 100 ml vial}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rheumocam 5 mg/ml solution for injection for dogs and cats
Meloxicam

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam: 5 mg/ml,
Ethanol (96%): 159.8 mg/ml.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

10 ml
20 ml
100 ml

5. TARGET SPECIES

Dogs and cats

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dogs: Musculo-skeletal disorders: single subcutaneous injection.
Post-operative pain: single intravenous or subcutaneous injection.

Cats: Post-operative pain: single subcutaneous injection.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in pregnant or lactating animals.

10. EXPIRY DATE

EXP {month/year}
Shelf life of broached vial: 28 days.

11. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway,
Ireland.

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/07/078/015 10 ml
EU/2/07/078/016 20 ml
EU/2/07/078/017 100ml

17. MANUFACTURER'S BATCH NUMBER

BN {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{Label for 100 ml vials}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rheumocam 5 mg/ml solution for injection for cats and dogs
Meloxicam

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam: 5 mg/ml,
Ethanol (96%): 159.8 mg/ml.

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Dogs and cats

6. INDICATIONS

Read package leaflet before use.

7. METHOD AND ROUTE OF ADMINISTRATION

Dogs: Musculo-skeletal disorders: single subcutaneous injection.
Post-operative pain: single intravenous or subcutaneous injection.

Cats: Post-operative pain: single subcutaneous injection.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the immediate packaging: 28 days.
Once broached, use by…

11. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF USUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS 'FOR ANIMAL TREATMENT ONLY' AND CONDITIONS OF RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co. Galway
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/07/078/017

17. MANUFACTURER'S BATCH NUMBER

BN {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Label for 10 ml and 20 ml vials}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rheumocam 5 mg/ml solution for injection for dogs and cats
Meloxicam

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 5 mg/ml.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml
20 ml

4. ROUTE(S) OF ADMINISTRATION

Dogs: IV or SC.
Cats: SC.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

BN {number}

7. EXPIRY DATE

EXP {month/year}
Once broached, use by…

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Carton for 20 ml, 50 ml and 100ml vial}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rheumocam 5 mg/ml solution for injection for cattle and pigs
Meloxicam

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam: 5 mg/ml
Ethanol (96%): 159.8 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

20 ml
50 ml
100 ml

5. TARGET SPECIES

Cattle (calves and young cattle) and pigs

6. INDICATION(S)

Cattle:

Acute respiratory infection.
Diarrhoea in calves of over one week of age and young, non-lactating cattle.

Pigs:

Non-infectious locomotor disorders.
Post operative pain associated with minor soft tissue surgery such as castration.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle:
Single subcutaneous or intravenous injection.

Pigs:
Single intramuscular injection. If required, a second administration can be given after 24 hours.

Single intramuscular injection before surgery.
Take care of accurate dosing, use of appropriate dosing devise and estimation of body weight.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period
Cattle: meat and offal: 15 days.
Pigs: meat and offal: 5 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf-life of broached vial: 28 days.
Once broached, use by……..

11. SPECIAL STORAGE CONDITIONS

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway,
Ireland.

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/07/078/018 20 ml
EU/2/07/078/019 50 ml
EU/2/07/078/020 100ml

17. MANUFACTURER'S BATCH NUMBER

BN {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{Label for 100 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rheumocam 5 mg/ml solution for injection for cattle and pigs
Meloxicam

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 5 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml,

5. TARGET SPECIES

Cattle (calves and young cattle) and pigs

6. INDICATIONS

Read package leaflet before use.

7. METHOD AND ROUTES OF ADMINISTRATION

Cattle: SC or IV injection.

Pigs: IM injection.

Read the package leaflet before use

8. WITHDRAWAL PERIOD(S)

Withdrawal period
Cattle: meat and offal: 15 days
Pigs: meat and offal: 5 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use

10. EXPIRY DATE

EXP {month/year}
Once broached, use by…

11. SPECIAL STORAGE CONDITIONS

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF USUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use

13. THE WORDS 'FOR ANIMAL TREATMENT ONLY' AND CONDITIONS OF RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only-to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co. Galway
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/07/078/020 100 ml

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Label for 20 ml and 50 ml bottles}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rheumocam 5 mg/ml Solution for injection for Cattle and Pigs
Meloxicam

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 5 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

20 ml
50 ml

4. ROUTES OF ADMINISTRATION

Cattle: SC or IV.
Pigs: IM.

5. WITHDRAWAL PERIOD(S)

Withdrawal period
Cattle: meat and offal: 15 days
Pigs: meat and offal: 5 days.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once broached use by …

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rheumocam 330 mg, granules for horses.
meloxicam

2. STATEMENT OF ACTIVE SUBSTANCES

One sachet contains: 330 mg of meloxicam.

3. PHARMACEUTICAL FORM

Granules in sachet

4. PACKAGE SIZE

100 sachets
10 sachets

5. TARGET SPECIES

Horses.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

In-feed use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period:
Meat and offal: 3 days.
Not authorised for use in lactating animals producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Each sachet contains one dose for a horse weighing 500 kg - 600 kg. The dose must not be divided.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway,
IRELAND.

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/07/078/021
EU/2/07/078/026

17. MANUFACTURER'S BATCH NUMBER

BN{number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Sachet

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rheumocam 330 mg, granules for horses.
meloxicam

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 330 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

4. ROUTE(S) OF ADMINISTRATION

In-feed use

5. WITHDRAWAL PERIOD(S)

Withdrawal period:
Meat and offal: 3 days.
Not authorised for use in lactating animals producing milk for human consumption.

6. BATCH NUMBER

BN {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rheumocam 0.5 mg/ml oral suspension for cats
meloxicam

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 0.5 mg/ml

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

3 ml
5 ml
10 ml
15 ml

5. TARGET SPECIES

Cats.

6. INDICATION(S)

7. METHOD AND ROUTE OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
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.

11. SPECIAL STORAGE CONDITIONS

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway,
IRELAND.

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/07/078/022	10 ml
EU/2/07/078/023	15 ml
EU/2/07/078/024	3 ml
EU/2/07/078/025	5 ml

17. MANUFACTURER'S BATCH NUMBER

BN{number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rheumocam 0.5 mg/ml oral suspension for cats
meloxicam

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 0.5 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

3 ml
5 ml
10 ml
15 ml

4. ROUTE OF ADMINISTRATION

Oral use

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

BN {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Rheumocam 1.5 mg/ml oral suspension for dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:
Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway,
Ireland.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rheumocam 1.5 mg/ml oral suspension for dogs

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains: 1.5 mg of meloxicam,
5 mg of sodium benzoate.

4. INDICATION(S)

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

5. 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 case of hypersensitivity.
Do not use in dogs less than 6 weeks of age.

6. ADVERSE REACTIONS

Typical adverse reactions of non-steroidal anti-inflammatory drugs (NSAIDs) such as loss of appetite, vomiting, diarrhoea, faecal occult blood lethargy and renal failure have occasionally 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.

If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- 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 you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

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

Shake well before use. To be administered mixed with food.
Avoid introduction of contamination during use.
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.
The suspension can be given using the measuring syringe provided in the package. The syringe has a scale which corresponds to the volume required.
The following dosing table indicates what volume to administer depending on the weight of the dog:

Bodyweight (kg)	Maintenance dosage (ml)
7.5	0.5
15	1
22.5	1.5
30	2
37.5	2.5
45	3
52.5	3.5
60	4

For the first day, twice the maintenance dosage will be required.
A clinical response is normally seen within 3 to 4 days. Treatment should be discontinued after 10 days at the latest if no clinical improvement is apparent.

Please follow these steps:

Step 1. Before using Rheumocam for the very first time ensure that you have the bottle, circular plastic insert and syringe.

Step 2. Place the circular plastic insert into the neck of the bottle and push down until securely in place. Once in place the insert will not need to be removed.

Step 3.
Replace the cap on the bottle and shake it well. Take off the bottle cap and attach the dosing syringe to the bottle by gently pushing the end into the hole.

Step 4.
Turn the bottle with the syringe in place upside down and slowly withdraw the plunger until the required dose is evident.

Step 5. Turn the bottle/syringe the right way up and with a twisting movement separate the syringe from the bottle.

Step 6. Push the plunger until all contents of the syringe have been dispensed onto the food.

9. ADVICE ON CORRECT ADMINISTRATION

Particular care should be taken with regard to the accuracy of dosing. Please carefully follow the instructions of the veterinarian.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

This veterinary medicinal product does not require any special storage conditions.
Keep out of the sight and reach of children.
Do not use after the expiry date (EXP) stated on the carton and the bottle.

12. SPECIAL WARNING(S)

If side effects occur, treatment should be discontinued and the advice of a veterinarian should be sought. Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity. This product for dogs should not be used in cats as it is not suitable for use in this species. In cats, Rheumocam 0.5 mg/ml oral suspension for cats should be used.

Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects. Rheumocam must not be administered in conjunction with other NSAIDs or glucocorticosteriods.

Pre-treatment with anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such veterinary products should be observed for at least 24 hours before commencement of treatment. The treatment-free period, however, should take into account the pharmacokinetic properties of the veterinary products used previously.

In the case of overdosage symptomatic treatment should be initiated.

People with known hypersensitivity to NSAIDs should avoid contact with the veterinary medicinal product.

In case of accidental ingestion, seek medical advice immediately and show this package leaflet or the label to the physician.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu).

15. OTHER INFORMATION

To be supplied only on veterinary prescription.
15, 42, 100 or 200 ml bottle with two measuring syringes.
Not all pack sizes may be marketed.
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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E: info.vet@kela.health

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Sverige
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Kaptensgatan 12
SE-114 57 Stockholm

United Kingdom (Northern Ireland)
Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
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Tel: + 353 91 841788

PACKAGE LEAFLET:
Rheumocam 1 mg chewable tablets for dogs
Rheumocam 2.5 mg chewable tablets for dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:
Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea,
Co. Galway,
Ireland.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rheumocam 1 mg chewable tablets for dogs
Rheumocam 2.5 mg chewable tablets for dogs
Meloxicam

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each chewable tablet contains:

Active substance:
Meloxicam 1 mg
Meloxicam 2.5 mg

4. INDICATION(S)

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

5. 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 dogs less than 6 weeks of age or less than 4 kg body weight.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

Typical adverse drug reactions of non-steroidal anti-inflammatory drugs such as loss of appetite, vomiting, diarrhoea, faecal occult blood, apathy and renal failure have occasionally 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.

If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- 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 you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

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

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.
Each chewable tablet contains either 1 mg or 2.5 mg meloxicam, which corresponds to the daily maintenance dose for a 10 kg body weight dog, or a 25 kg body weight dog respectively. Each chewable tablet can be halved for accurate dosing according to the individual body weight of the animal. Rheumocam chewable tablets can be administered with or without food, are flavoured and are taken by most dogs voluntarily.
Dose scheme for the maintenance dose:

Body weight (kg)	Number of chewable tablets		mg/kg
	1 mg	2.5 mg	
4.0–7.0	½		0.13–0.1
7.1–10.0	1		0.14–0.1
10.1–15.0	1½		0.15–0.1
15.1–20.0	2		0.13–0.1
20.1–25.0		1	0.12–0.1
25.1–35.0		1½	0.15–0.1
35.1–50.0		2	0.14–0.1

The use of Rheumocam oral suspension for dogs may be considered for an even more precise dosing. For dogs weighing less than 4 kg the use of Rheumocam oral suspension for dogs is recommended.

A clinical response is normally seen within 3–4 days. Treatment should be discontinued after 10 days if no clinical improvement is apparent.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure correct dosage, body weight should be determined as accurately as possible to avoid underdosing or overdosing.

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.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of renal toxicity.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to NSAIDs should avoid contact with the veterinary medicinal product.
In case of accidental ingestion, seek medical advice immediately and show this package leaflet or the label to the physician.

Use during pregnancy and lactation:
See section "5. 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. Rheumocam 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 drugs should be observed for at least 24 hours before commencement of treatment. The treatment-free period, however, should take into account the pharmacokinetic properties of the products used previously.

Overdose (symptoms, emergency procedures, antidotes):
In the case of overdosage symptomatic treatment should be initiated.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu).

15. OTHER INFORMATION

20 tablets
100 tablets
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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PACKAGE LEAFLET:
Rheumocam 15 mg/ml oral suspension for horses

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:
Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway,
Ireland.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rheumocam 15 mg/ml oral suspension for horses
Meloxicam

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains: 15 mg of meloxicam,
5 mg of sodium benzoate.

4. INDICATION(S)

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

5. CONTRAINDICATIONS

Do not use in pregnant or lactating mares.
Do not use in horses 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 horses less than 6 weeks of age.

6. ADVERSE REACTIONS

Isolated cases of adverse reactions typically associated with non-steroidal anti-inflammatory drugs (NSAIDs) were observed in clinical trials (slight urticaria, diarrhoea). Symptoms were reversible. In very rare cases loss of appetite, lethargy, abdominal pain and colitis have been reported.
In very rare cases anaphylactoid reactions, which may be serious (including fatal), may occur and should be treated symptomatically.

If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- 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 you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses.

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

Oral suspension to be administered at a dosage of 0.6 mg/kg body weight, once daily, up to 14 days. This is equivalent to 1 ml of Rheumocam per 25 kg body weight of horse. For example, a horse weighing 400 kg will receive 16 ml of Rheumocam, a horse weighing 500 kg will receive 20 ml of Rheumocam, and a horse weighing 600 kg will receive 24 ml of Rheumocam.

Shake well before use. To be administered either mixed with a small quantity of food, prior to feeding, or directly into the mouth.

The suspension should be given using the measuring syringe provided in the package. The syringe fits onto the bottle and has a 2 ml scale.

Avoid introduction of contamination during use.

<table>
<tr><td colspan="4">Please follow these steps:</td></tr>
<tr><td>Step 1. Before using Rheumocam for the very first time ensure that you have the bottle, circular plastic insert and syringe.</td><td>  </td><td>Step 2. Place the circular plastic insert into the neck of the bottle and push down until securely in place. Once in place the insert will not need to be removed</td><td>  </td></tr>
<tr><td>Step 3.
Replace the cap on the bottle and shake it well. Take off the bottle cap and attach the dosing syringe to the bottle by gently pushing the end into the hole.</td><td>  </td><td>Step 4.
Turn the bottle with the syringe in place upside down and slowly withdraw the plunger until the required dose is evident.</td><td>  </td></tr>
</table>

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 3 days.
Not authorised for use in lactating animals producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
After administration of the veterinary medicinal product, close the bottle by replacing the cap, wash the measuring syringe with warm water and let it dry.
Do not use after the expiry date (EXP) stated on the carton and the bottle.
Shelf life after first opening of the container: 3 months.

12. SPECIAL WARNING(S)

Special precautions for use in animals:

If side effects occur, treatment should be discontinued and the advice of a veterinarian should be sought.
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 NSAIDs should avoid contact with the veterinary medicinal product.
In case of accidental ingestion, seek medical advice immediately and show this package leaflet or the label to the physician.

Use during pregnancy and lactation:

See the section under “Contraindications”.

Interaction with other medicinal products and other forms of interaction:

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

Overdose (symptoms, emergency procedures, antidotes):

In the case of overdose symptomatic treatment should be initiated.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu).

15. OTHER INFORMATION

To be supplied only on veterinary prescription.
100 or 250 ml bottle with a measuring syringe.
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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E: info.vet@kela.health

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PACKAGE LEAFLET:
Rheumocam 20 mg/ml solution for injection for cattle, pigs and horses

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland

Manufacturers responsible for the batch release:
Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland

and

Eurovet Animal Health B.V., Handelsweg 25, 5531 AE Bladel, The Netherlands

and

Labiana Life Sciences, S.A., C/ Venus, 26, Pol. Ind. Can Parellada, Tarrasa, 08228 Barcelona

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rheumocam 20 mg/ml solution for injection for cattle, pigs and horses
Meloxicam

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

One ml contains:

Meloxicam 20 mg
Ethanol (96 percent) 159.8 mg
Clear, yellow solution.

4. INDICATION(S)

Cattle:

For use in acute respiratory infection with appropriate antibiotic therapy to reduce clinical signs in cattle.
For use in diarrhoea in combination with oral re-hydration therapy to reduce clinical signs in calves of over one week of age and young, non-lactating cattle.
For adjunctive therapy in the treatment of acute mastitis, in combination with antibiotic therapy.

Pigs:

For use in non-infectious locomotor disorders to reduce the symptoms of lameness and inflammation.
For adjunctive therapy in the treatment of puerperal septicaemia and toxaemia (mastitis-metritis-agalactia syndrome) with appropriate antibiotic therapy.

Horses:

For use in the alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders.
For the relief of pain associated with equine colic.

5. CONTRAINDICATIONS

Do not use in horses less than 6 weeks of age.
Do not use in pregnant or lactating mares.
Do not use in animals suffering from impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of ulcerogenic gastrointestinal lesions.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
For the treatment of diarrhoea in cattle, do not use in animals of less than one week of age.

6. ADVERSE REACTIONS

In cattle and pigs, subcutaneous, intramuscular as well as intravenous administration is well tolerated; only a slight transient swelling at the injection site following subcutaneous administration was observed in less than 10 % of the cattle treated in clinical studies.
In horses, a transient swelling at the injection site can occur but resolves without intervention.
In very rare cases anaphylactoid reactions, which may be serious (including fatal), may occur and should be treated symptomatically.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- 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 you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle, pigs and horses.

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

Cattle:

Single subcutaneous or intravenous injection at a dosage of 0.5 mg meloxicam/kg body weight (i.e. 2.5 ml/100 kg body weight) in combination with antibiotic therapy or with oral re-hydration therapy, as appropriate.

Pigs:

Single intramuscular injection at a dosage of 0.4 mg meloxicam/kg body weight (i.e. 2.0 ml/100 kg body weight) in combination with antibiotic therapy, as appropriate. If required, a second administration of meloxicam can be given after 24 hours.

Horses:

Single intravenous injection at a dosage of 0.6 mg meloxicam/kg body weight (i.e. 3.0 ml/100 kg body weight).
For use in the alleviation of inflammation and the relief of pain in both acute and chronic musculoskeletal disorders, Rheumocam 15 mg/ml oral suspension may be used for continuation of treatment at a dosage of 0.6 mg meloxicam/kg body weight, 24 hours after administration of the injection.

9. ADVICE ON CORRECT ADMINISTRATION

Avoid introduction of contamination during use.
Maximum number of piercings is 14 for the 20 ml, 50 ml and 100 ml stoppers and 20 for the 250 ml stopper.

10. WITHDRAWAL PERIOD(S)

Cattle: meat and offal: 15 days; milk: 5 days.
Pigs: meat and offal: 5 days.
Horses: meat and offal: 5 days.
Not authorised for use in horses producing milk for human consumption.

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 after the expiry date (EXP) stated on the carton and vial.
Shelf life after first opening the container: 28 days.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.
Avoid use in very severely dehydrated, hypovolaemic or hypotensive animals which require parenteral rehydration, as there may be a potential risk of renal toxicity.
In case of inadequate relief of pain when used in the treatment of equine colic, careful re-evaluation of the diagnosis should be made as this could indicate the need for surgical intervention.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
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 this package leaflet or the label to the physician.

Use during pregnancy and lactation:
Cattle and pigs**:** Can be used during pregnancy and lactation.
Horses: See section "Contraindications".

Interaction with other medicinal products and other forms of interaction:
Do not administer concurrently with glucocorticosteroids, other non-steroidal anti-inflammatory drugs or with anti-coagulant agents.

Overdose (symptoms, emergency procedures, antidotes):
In the case of overdose, symptomatic treatment should be initiated.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Waste materials should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. OTHER INFORMATION

Cardboard box containing one colourless glass injection vial of 20 ml, 50 ml, 100 ml or 250 ml.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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PACKAGE LEAFLET:
Rheumocam 5 mg/ml solution for injection for dogs and cats

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea, Co. Galway,
Ireland

Manufacturers responsible for the batch release:
Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea, Co. Galway,
Ireland

and

Eurovet Animal Health B.V.
Handelsweg 25, 5531 AE Bladel,
The Netherlands

and

Labiana Life Sciences, S.A.,
C/ Venus, 26, Pol. Ind. Can Parellada, Tarrasa,
08228 Barcelona

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rheumocam 5 mg/ml solution for injection for dogs and cats
Meloxicam

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

One ml contains:

Meloxicam 5 mg,
Ethanol (96%) 159.8 mg.
Clear, yellow solution.

4. INDICATION(S)

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.

5. 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.

6. ADVERSE REACTIONS

Typical adverse reactions of non-steroidal anti-inflammatory drugs (NSAIDs) such as loss of appetite, vomiting, diarrhoea, faecal occult blood, apathy and renal failure, have occasionally been reported. In very rare cases elevated liver enzymes have been reported.

In very rare cases, haemorrhagic diarrhoea, haematemesis, and gastrointestinal ulceration 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.
In very rare cases, anaphylactoid reactions may occur and should be treated symptomatically.
If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- 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 you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs and cats.

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

Dosage for each species:

Dogs: single administration of 0.2 mg meloxicam /kg body weight (i.e. 0.4 ml/10 kg).
Cats: single administration of 0.3 mg meloxicam/kg body weight (i.e. 0.06 ml/kg).

Method and routes of administration:

Dogs:
Musculo-skeletal disorders: single subcutaneous injection.
Rheumocam 1.5 mg/ml oral suspension for dogs or Rheumocam 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 before surgery, for example, at the time of induction of anaesthesia.

Cats:
Reduction of post-operative pain after ovariohysterectomy and minor soft tissue surgery: single subcutaneous injection before surgery, for example, at the time of induction of anaesthesia.

9. ADVICE ON CORRECT ADMINISTRATION

Particular care should be taken with regard to the accuracy of dosing.
Avoid introduction of contamination during use.
Maximum number of piercings is 42 for all presentations.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Keep the vial in the outer carton.
Do not use after the expiry date (EXP) stated on the carton and vial.
Shelf life after first opening the container: 28 days.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.
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 Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) should not be administered in cats, as appropriate dosage regimens for such follow-up treatments have not been established.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
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 this package leaflet or the label to the physician.

Use during pregnancy and lactation:
Do not use in pregnant or lactating animals.

Interaction with other medicinal products and other forms of interaction:
Other NSAIDs, diuretics, anti-coagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects. Rheumocam 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. The treatment-free period, however, should take into account the pharmacological properties of the products used previously.

Overdose (symptoms, emergency procedures, antidotes):
In the case of overdose, symptomatic treatment should be initiated.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. OTHER INFORMATION

Carton box containing one colourless glass injection vial of 10 ml, 20 ml or 100ml, closed with a bromobutyl rubber stopper and sealed with an aluminium cap.
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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PACKAGE LEAFLET:
Rheumocam 5 mg/ml solution for injection for cattle and pigs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland

Manufacturers responsible for the batch release:
Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland

and

Eurovet Animal Health B.V., Handelsweg 25, 5531 AE Bladel, The Netherlands

and

Labiana Life Sciences, S.A., C/ Venus, 26, Pol. Ind. Can Parellada, Tarrasa, 08228 Barcelona

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rheumocam 5 mg/ml solution for injection for cattle and pigs
Meloxicam

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

One ml contains:

Meloxicam	5 mg
Ethanol (96%)	159.8 mg

Clear, yellow solution.

4. INDICATION(S)

Cattle:

For use in acute respiratory infection with appropriate antibiotic therapy to reduce clinical signs in cattle.
For use in diarrhoea in combination with oral re-hydration therapy to reduce clinical signs in calves of over one week of age and young, non-lactating cattle.

Pigs:

For use in non-infectious locomotor disorders to reduce the symptoms of lameness and inflammation.
For the relief of post operative pain associated with minor soft tissue such as castration.

5. CONTRAINDICATIONS

Do not use in animals suffering from impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of ulcerogenic gastrointestinal lesions.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
For the treatment of diarrhoea in cattle, do not use in animals of less than one week of age.
Do not use in pigs less than 2 days old.

6. ADVERSE REACTIONS

Subcutaneous, intramuscular as well as intravenous administration is well tolerated; only a slight transient swelling at the injection site following subcutaneous administration was observed in less than 10 % of the cattle treated in clinical studies.

In very rare cases anaphylactoid reactions which may be serious (including fatal) may occur and should be treated symptomatically.

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 you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle (calves and young cattle) and pigs.

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

Cattle:

Single subcutaneous or intravenous injection at a dosage of 0.5 mg meloxicam/kg body weight (i.e. 10 ml/100 kg body weight) in combination with antibiotic therapy or with oral re-hydration therapy, as appropriate.

Pigs:

Locomotor disorders:
Single intramuscular injection at a dosage of 0.4 mg meloxicam/kg body weight (i.e. 2.0 ml/25 kg body weight). If required, a second administration of meloxicam can be given after 24 hours.

Reduction of post-operative pain:
Single intramuscular injection at a dosage of 0.4 mg meloxicam/kg body weight (i.e. 0.4 ml/5 kg body weight) before surgery.

Particular care should be taken with regard to the accuracy of dosing including the use of an appropriate dosing device and careful estimation of bodyweight.

9. ADVICE ON CORRECT ADMINISTRATION

Avoid introduction of contamination during use.

10. WITHDRAWAL PERIOD(S)

Cattle: meat and offal: 15 days.
Pigs: meat and offal: 5 days.

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 after the expiry date (EXP) stated on the carton and vial.
Shelf life after first opening the container: 28 days.

12. SPECIAL WARNING(S)

Treatment of piglets with Rheumocam before castration reduces post-operative pain. To obtain pain relief during surgery co-medication with an appropriate anaesthetic/sedative is needed.

To obtain the best possible relieving effect post surgery Rheumocam should be administered 30minutes before surgical intervention.

Special precautions for use in animals:
If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.
Avoid use in very severely dehydrated, hypovolaemic or hypotensive animals 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:
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 this package leaflet or the label to the physician.

Use during pregnancy and lactation:
Cattle**:** Can be used during pregnancy.
Pigs**:** 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.

Overdose (symptoms, emergency procedures, antidotes):
In the case of overdose symptomatic treatment should be initiated.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Waste materials should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu).

15. OTHER INFORMATION

Cardboard box containing 1 colourless glass injection vial of 20 ml, 50 ml or 100 ml.
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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PACKAGE LEAFLET:
Rheumocam 330 mg granules for horses

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:
Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway,
IRELAND.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rheumocam 330 mg granules for horses.
Meloxicam

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

One sachet contains: 330 mg of meloxicam.
Pale yellow granules.

4. INDICATION(S)

Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in horses weighing between 500 and 600 kg.

5. CONTRAINDICATIONS

Do not use in pregnant or lactating mares.
Do not use in horses 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 horses less than 6 weeks of age.

6. ADVERSE REACTIONS

Isolated cases of adverse reactions typically associated with non-steroidal anti-inflammatory drugs (NSAIDs) were observed in clinical trials (slight urticaria, diarrhoea). Symptoms were reversible. In very rare cases loss of appetite, lethargy, abdominal pain and colitis have been reported.

In very rare cases anaphylactoid reactions, which may be serious (including fatal), may occur and should be treated symptomatically.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- 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.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses.

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

In-feed use.

To be administered mixed with food at a dose of 0.6 mg/kg body weight, once daily, up to 14 days.
The product should be added to 250 g of muesli feed, prior to feeding.

Each sachet contains one dose for a horse weighing between 500 kg and 600 kg and the dose must not be divided into smaller doses.

9. ADVICE ON CORRECT ADMINISTRATION

Avoid introduction of contamination during use.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 3 days.
Not authorised for use in lactating animals producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the sachet after EXP.
Shelf life after incorporation into muesli feed: use immediately.

12. SPECIAL WARNING(S)

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.

In order to minimise risk of intolerance, the product should be mixed into muesli feed.

This product is only for use in horses weighing between 500 and 600 kg.

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.
In case of accidental ingestion, seek medical advice immediately and show this package leaflet or the label to the physician.

Pregnancy and lactation:
Do not use in pregnant or lactating mares.

Interaction with other medicinal products and other forms of interaction:
Do not administer concurrently with glucocorticoids, other NSAIDs or with anti-coagulant agents.

Overdose (symptoms, emergency procedures, antidotes):
In the case of overdose symptomatic treatment should be initiated.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu).

15. OTHER INFORMATION

Pack size: 100, 10 sachets.
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:
Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway,
IRELAND.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rheumocam 0.5 mg/ml oral suspension for cats.
meloxicam

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

One ml contains:

Active substance
Meloxicam 0.5 mg.

Excipient
Sodium benzoate 1.5 mg.

Smooth light yellow suspension.

4. INDICATION(S)

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. ADVERSE REACTIONS

Typical adverse reactions of non-steroidal anti-inflammatory drugs (NSAIDs) such as loss of appetite, vomiting, diarrhoea, faecal occult blood, lethargy and renal failure have occasionally been reported. Gastrointestinal ulceration and elevated liver enzymes were reported in very rare cases.

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.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- 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 you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cats.

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 Rheumocam 5 mg/ml solution for injection for cats, continue treatment 24 hours later with Rheumocam 0.5 mg/ml oral suspension for cats at a dosage of 0.05 mg meloxicam/kg body weight. The oral follow-up dose may be administered once daily (at 24-hour intervals) for up to 4 days.

Acute musculo-skeletal disorders:
Initial treatment is a single oral 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 dose of 0.05 mg meloxicam/kg body weight 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 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.
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
To be administered orally either mixed with food or directly into the mouth.
The syringe fits onto the drop dispenser of the bottle and has a kg-body weight scale which corresponds to the dose of 0.05 mg meloxicam/kg bodyweight. Thus for initiation of the treatment of chronic musculo-skeletal disorders on the first day, twice the maintenance volume will be required. For initiation of the treatment of acute musculo-skeletal disorders on the first day, 4 times the maintenance volume will be required.

9. ADVICE ON CORRECT ADMINISTRATION

Particular care should be taken with regard to the accuracy of dosing. The recommended dose should not be exceeded.
Please carefully follow the instructions of the veterinarian.
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 WARNING(S)

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 pain and inflammation following surgical procedures:
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.
In case of accidental ingestion, seek medical advice immediately and show this package leaflet or the label to the physician.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during 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. Rheumocam must not be administered in conjunction with other NSAIDs or glucocorticosteroids. Concurrent administration of potential nephrotoxic veterinary medicinal products should be avoided.

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.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu).

15. OTHER INFORMATION

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.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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