ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Melosus 1.5 mg/ml oral suspension for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Meloxicam 1.5 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Sodium benzoate	1.75 mg
Sorbitol	
Glycerol	
Polysorbate 80	
Disodium phosphate dodecahydrate	
Silica, colloidal anhydrous	
Hydroxyethylcellulose	
Citric acid monohydrate	
Sodium cyclamate	
Sucralose	
Anise aroma	
Water, purified	

Yellow/green suspension.

3. CLINICAL INFORMATION

3.1 Target species

Dogs

3.2 Indications for use for each target species

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

3.3 Contraindications

Do not use in:
- dogs suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
- cases of hypersensitivity to the active substance or to any of the excipients.

- dogs less than 6 weeks of age.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity.
This veterinary medicinal product for dogs should not be used in cats as it is not suitable for use in this species. In cats, Melosus 0.5 mg/ml oral suspension 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.

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

3.6 Adverse events

Dogs:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Appetite loss[1], lethargy[1] Vomiting[1], diarrhoea [1], blood in faeces[1,2], Haemorrhagic diarrhoea [1], haematemesis[1], gastric ulcer[1], small intestine ulcer[1] Elevated liver enzymes[1] Renal failure[1]

[1] Occur generally within the first treatment week, most cases are transient and disappear following termination of the treatment. In very rare cases may be serious or fatal.
[2] Occult

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

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 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.

3.8 Interaction with other medicinal products and other forms of interaction

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

Pre-treatment with anti-inflammatory substances, other than meloxicam solution for injection, 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 pharmacokinetic properties of the products used previously.

3.9 Administration routes and dosage

Oral use.
To be administered either mixed with food or directly into the mouth.
Shake well before 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.

For longer term treatment, once clinical response has been observed (after ≥ 4 days), the dose of the veterinary medicinal product can be adjusted to the lowest effective individual dose reflecting that the degree of pain and inflammation associated with chronic musculo-skeletal disorders may vary over time.

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

The suspension can be given using the measuring syringe provided in the package.
The syringe fits onto the drop dispenser of the bottle and has a kg-body weight scale which corresponds to the maintenance dose. Thus, for initiation of the therapy on 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.

Avoid introduction of contamination during use.

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

In case of overdose symptomatic treatment should be initiated.

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

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AC06

4.2 Pharmacodynamics

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

4.3 Pharmacokinetics

Absorption
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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after first opening the immediate packaging: 6 months

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Polyethylene bottle containing 10 ml, 25 ml, 50 ml or 125 ml with a tamper proof child resistant closure and a polypropylene measuring syringe in a cardboard box.

Not all pack sizes may be marketed.

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

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

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

6. NAME OF THE MARKETING AUTHORISATION HOLDER

CP-Pharma Handelsgesellschaft mbH

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/10/116/005 (10 ml)
EU/2/10/116/001 (25 ml)
EU/2/10/116/002 (50 ml)
EU/2/10/116/003 (125 ml)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 21/02/2011

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

DD/MM/YYYY

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Melosus 0.5 mg/ml oral suspension for cats and guinea pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Meloxicam 0.5 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Sodium benzoate	1.75 mg
Sorbitol	
Glycerol	
Polysorbate 80	
Disodium phosphate dodecahydrate	
Silica, colloidal anhydrous	
Hydroxyethylcellulose	
Citric acid monohydrate	
Sodium cyclamate	
Sucralose	
Anise aroma	
Water, purified	

Yellow/green suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cats and guinea pigs

3.2 Indications for use for each target species

Cats:
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.

Guinea pigs:
Alleviation of mild to moderate post-operative pain associated with soft tissue surgery such as male castration.

3.3 Contraindications

Do not use in:
- cats suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
- cases of hypersensitivity to the active substance or to any of the excipients.
- cats less than 6 weeks of age.
- guinea pigs less than 4 weeks of age.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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

Post-operative use in cats and guinea pigs:
In case additional pain relief is required, multimodal pain therapy should be considered.

Chronic musculoskeletal disorders in cats:
Response to long-term therapy should be monitored at regular intervals by a veterinary surgeon.

The veterinary medicinal product should not be used following parenteral injection of meloxicam or any other Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) as appropriate dosage regimens for such follow-up treatments have not been established in cats.

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 the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cats:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Appetite loss[1], lethargy[1] Vomiting[1], diarrhoea[1], blood in faeces[1,2], haemorrhagic diarrhoea[1], haematemesis[1], gastric ulcer[1], small intestine ulcer[1] Elevated liver enzymes[1] Renal failure[1]

[1] Occur generally within the first treatment week, most cases are transient and disappear following termination of the treatment. In very rare cases may be serious or fatal.

[2] Occult

Guinea pigs: None.

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

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 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.

3.8 Interaction with other medicinal products and other forms of interaction

Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects. This veterinary medicinal product 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, other than meloxicam solution for injection, 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 pharmacokinetic properties of the products used previously.

3.9 Administration routes and dosage

Oral use.
To be administered either mixed with food or directly into the mouth.
Shake well before use.
Avoid introduction of contamination during use.

Cats:
Dosage
Post-operative pain and inflammation following surgical procedures:
After initial treatment with meloxicam solution for injection for cats, continue treatment 24 hours later with this veterinary medicinal product 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 bodyweight 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 suspension can be given using the measuring syringe provided in the package. The syringe fits onto the drop dispenser of the bottle and has a kg-body weight scale which corresponds to the maintenance dose. 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. Particular care should be taken with regard to the accuracy of dosing. The recommended dose should not be exceeded.

Guinea pigs:
Dosage
Post-operative pain associated with soft tissue surgery:
Initial treatment is a single oral dose of 0.2 mg meloxicam/kg body weight on day 1 (pre-surgery). Treatment is to be continued once daily by oral administration (at 24-hours intervals) at a dose of 0.1 mg meloxicam/kg body weight on day 2 to day 3 (post-surgery).

The dose can, at the discretion of the veterinarian, be titrated up to 0.5 mg/kg in individual cases. The safety of doses exceeding 0.6 mg/kg has, however, not been evaluated in guinea pigs.

Route and method of administration
The suspension should be given directly into the mouth using a standard 1 ml syringe graduated with ml scale and 0.01 ml increments.

Dose of 0.2 mg meloxicam/kg body weight: 0.4 ml/kg body weight
Dose of 0.1 mg meloxicam/kg body weight: 0.2 ml/kg body weight

Use a small container (e.g. a teaspoon) and drop the veterinary medicinal product into the container (it is advised to dispense a few drops more than required into the small container). Use a standard 1 ml syringe to draw up the veterinary medicinal product according to the bodyweight of the guinea pig. Administer the veterinary medicinal product with the syringe directly into the mouth of the guinea pig. Wash the small container with water and dry prior to the next use.

Do not use the cat syringe with the kg-body weight scale for guinea pigs.

3.10 Symptoms of overdose (and where applicable, emergency procedures and 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 3.6, are expected to be more severe and more frequent. In case of overdose symptomatic treatment should be initiated.

In guinea pigs, an overdose of 0.6 mg/kg body weight administered during 3 days followed by a dose of 0.3 mg/kg during 6 additional days did not cause adverse events typical for meloxicam. The safety of doses exceeding 0.6 mg/kg has not been evaluated in guinea pigs.

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

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AC06

4.2 Pharmacodynamics

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

4.3 Pharmacokinetics

Cats:
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. 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. Due to the loading dose, steady state is reached after 2 days (48h).

Guinea pigs:
No data available.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale:	3 years
Shelf life after first opening the immediate packaging:	6 months

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Polyethylene bottle containing 5 ml, 10 ml or 25 ml with a tamper proof child resistant closure and a polypropylene measuring syringe in a cardboard box.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

CP-Pharma Handelsgesellschaft mbH

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/10/116/007 (5 ml)
EU/2/10/116/006 (10 ml)
EU/2/10/116/004 (25 ml)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 21/02/2011

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

DD/MM/YYYY

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Melosus 1.5 mg/ml oral suspension for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 1.5 mg/ml

3. PACKAGE SIZE

10 ml
25 ml
50 ml
125 ml

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Shake well before use.
Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use by _____

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

CP-Pharma Handelsgesellschaft mbH

14. MARKETING AUTHORISATION NUMBERS

EU/2/10/116/005 10 ml
EU/2/10/116/001 25 ml
EU/2/10/116/002 50 ml
EU/2/10/116/003 125 ml

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle (125 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Melosus 1.5 mg/ml oral suspension for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 1.5 mg/ml

125ml

3. TARGET SPECIES

Dogs.

4. ROUTES OF ADMINISTRATION

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

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use by _____

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

CP-Pharma Handelsgesellschaft mbH

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle (10, 25 and 50 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Melosus 1.5 mg/ml oral suspension for dogs

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Meloxicam 1.5 mg/ml

10 ml
25 ml
50 ml

Shake well before use.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use by _____

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Melosus 0.5 mg/ml oral suspension for cats and guinea pigs

2. STATEMENT OF ACTIVE SUBSTANCES

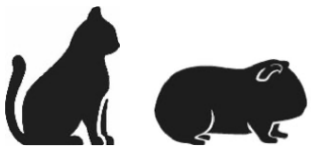
Meloxicam 0.5 mg/ml

3. PACKAGE SIZE

5 ml
10 ml
25 ml

4. TARGET SPECIES

Cats and guinea pigs



5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Shake well before use.
Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use by _____

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

CP-Pharma Handelsgesellschaft mbH

14. MARKETING AUTHORISATION NUMBERS

EU/2/10/116/007 5 ml
EU/2/10/116/006 10 ml
EU/2/10/116/004 25 ml

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle (5, 10 and 25 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Melosus 0.5 mg/ml oral suspension for cats and guinea pigs

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Meloxicam 0.5 mg/ml

5 ml
10 ml
25 ml

Shake well before use.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use by _____

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Melosus 1.5 mg/ml oral suspension for dogs

2. Composition

Each ml contains:

Active substances:
Meloxicam 1.5 mg/ml

Excipients:
Sodium benzoate 1.75 mg/ml

Yellow/green suspension.

3. Target species

Dogs

4. Indications for use

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

5. Contraindications

Do not use in:
- dogs suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
- cases of hypersensitivity to the active substance or to any of the excipients.
- dogs less than 6 weeks of age.

6. Special warnings

Special precautions for safe use in the target species:

Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity.
This veterinary medicinal product for dogs should not be used in cats as it is not suitable for use in this species. In cats, Melosus 0.5 mg/ml oral suspension 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.

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

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. This veterinary medicinal product must not be administered in conjunction with other NSAIDs or glucocorticosteroids.

Pre-treatment with anti-inflammatory substances, other than meloxicam solution for injection, 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:

In case of overdose symptomatic treatment should be initiated.

Major incompatibilities:

None known.

7. Adverse events

Dogs:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Appetite loss[1], lethargy[1] Vomiting[1], diarrhoea [1], blood in faeces[1,2], Haemorrhagic diarrhoea [1], haematemesis[1], gastric ulcer[1], small intestine ulcer[1] Elevated liver enzymes[1] Renal failure[1]

[1] Occur generally within the first treatment week, most cases are transient and disappear following termination of the treatment. In very rare cases may be serious or fatal.
[2] Occult

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

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

Oral use.
To be administered orally either mixed with food or directly into the mouth.
Shake well before use.

Dosage
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 maintenance dose of 0.1 mg meloxicam/kg body weight.

For longer term treatment, once clinical response has been observed (after ≥ 4 days), the dose of the veterinary medicinal product can be adjusted to the lowest effective individual dose reflecting that the degree of pain and inflammation associated with chronic musculo-skeletal disorders may vary over time.

Route and method of administration

The suspension can be given using the measuring syringe of the veterinary medicinal product provided in the package.
The syringe fits onto the drop dispenser of the bottle and has a kg-body weight scale which corresponds to the maintenance dose. Thus, for initiation of the therapy on 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.
After each dose, the tip of the syringe should be wiped and the bottle cap screwed back on tightly. The syringe should be stored in the carton box in between uses.
To avoid introduction of external contaminants during use, keep the provided syringe only for this product.

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 periods

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. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 6 months.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/10/116/005 (10 ml)
EU/2/10/116/001 (25 ml)
EU/2/10/116/002 (50 ml)
EU/2/10/116/003 (125 ml)

Polyethylene bottle containing 10 ml, 25 ml, 50 ml or 125 ml with a tamper proof child resistant closure and a polypropylene measuring syringe in a cardboard box.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

MM/YYYY

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

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Manufacturer responsible for batch release:

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PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Melosus 0.5 mg/ml oral suspension for cats and guinea pigs

2. Composition

Each ml contains:

Active substances:
Meloxicam 0.5 mg/ml

Excipients:
Sodium benzoate 1.75 mg/ml

Yellow/green suspension.

3. Target species

Cats and guinea pigs

4. Indications for use

Cats:
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.

Guinea pigs:
Alleviation of mild to moderate post-operative pain associated with soft tissue surgery such as male castration.

5. Contraindications

Do not use in:
- cats suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
- cases of hypersensitivity to the active substance or to any of the excipients.
- cats less than 6 weeks of age.
- guinea pigs less than 4 weeks of age.

6. Special warnings

Special precautions for safe use in the target species:

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

Post-operative use in cats and guinea pigs:
In case additional pain relief is required, multimodal pain therapy should be considered.

Chronic musculoskeletal disorders in cats:
Response to long-term therapy should be monitored at regular intervals by a veterinary surgeon.

The veterinary medicinal product should not be used following parenteral injection of meloxicam or any other Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) as appropriate dosage regimens for such follow-up treatments have not been established in cats.

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 the 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. Do not use in pregnant or lactating animals.

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. This veterinary medicinal product 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, other than meloxicam solution for injection, 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:

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.

In guinea pigs, an overdose of 0.6 mg/kg body weight administered during 3 days followed by a dose of 0.3 mg/kg during 6 additional days did not cause adverse events typical for meloxicam. The safety of doses exceeding 0.6 mg/kg has not been evaluated in guinea pigs.

Major incompatibilities:

None known.

7. Adverse events

Cats:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Appetite loss[1], lethargy[1] Vomiting[1], diarrhoea[1], blood in faeces[1,2], haemorrhagic diarrhoea[1], haematemesis[1], gastric ulcer[1], small intestine ulcer[1] Elevated liver enzymes[1] Renal failure[1]

[1] Occur generally within the first treatment week, most cases are transient and disappear following termination of the treatment. In very rare cases may be serious or fatal.
[2] Occult

Guinea pigs: None.

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

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

Oral use.
To be administered either mixed with food or directly into the mouth.
Shake well before use.

Cats:
Dosage
Post-operative pain and inflammation following surgical procedures:
After initial treatment with meloxicam solution for injection for cats, continue treatment 24 hours later with this veterinary medicinal product 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 bodyweight 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 suspension can be given using the measuring syringe provided in the package.

The syringe fits onto the drop dispenser of the bottle and has a kg-body weight scale which corresponds to the maintenance dose. 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.

After each dose, the tip of the syringe should be wiped and the bottle cap screwed back on tightly. The syringe should be stored in the carton box in between uses.
To avoid introduction of external contaminants during use, keep the provided syringe only for this product.

Guinea pigs:
Dosage
Post-operative pain associated with soft tissue surgery:
Initial treatment is a single oral dose of 0.2 mg meloxicam/kg body weight on day 1 (pre-surgery). Treatment is to be continued once daily by oral administration (at 24-hours intervals) at a dose of 0.1 mg meloxicam/kg body weight on day 2 to day 3 (post-surgery).

The dose can, at the discretion of the veterinarian, be titrated up to 0.5 mg/kg in individual cases. The safety of doses exceeding 0.6 mg/kg has, however, not been evaluated in guinea pigs.

Route and method of administration
The suspension should be given directly into the mouth using a standard 1 ml syringe graduated with ml scale and 0.01 ml increments.

Dose of 0.2 mg meloxicam/kg body weight: 0.4 ml/kg body weight
Dose of 0.1 mg meloxicam/kg body weight: 0.2 ml/kg body weight

Use a small container (e.g. a teaspoon) and drop the veterinary medicinal product into the container (it is advised to dispense a few drops more than required into the small container). Use a standard 1 ml syringe to draw up the veterinary medicinal product according to the bodyweight of the guinea pig. Administer the veterinary medicinal product with the syringe directly into the mouth of the guinea pig. Wash the small container with water and dry prior to the next use.

Do not use the cat syringe with the kg-body weight scale for guinea pigs.

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 periods

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 bottle after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 6 months.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/10/116/007 5 ml
EU/2/10/116/006 10 ml
EU/2/10/116/004 25 ml

Polyethylene bottle containing 5 ml, 10 ml or 25 ml bottle with a tamper proof child resistant closure and a polypropylene measuring syringe in a cardboard box.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

DD/YYYY

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

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Ostlandring 13
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Manufacturer responsible for batch release:

Produlab Pharma B.V.
Forellenweg 16
4941 SJ Raamsdonksveer
The Netherlands

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