

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

One ml contains:

Active substance:

Meloxicam 1.5 mg

Excipient:

Sodium benzoate 1.75 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension.

Yellow/green 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 dogs suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

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

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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

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 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, 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 adverse reactions 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).

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 (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. Melosus 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 pharmacokinetic properties of the products used previously.

4.9 Amounts to be administered and administration route

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 Melosus 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.

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

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)
ATC vet code: QM01AC06

5.1 Pharmacodynamic properties

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

5.2 Pharmacokinetic particulars

Absorption

Meloxicam is completely absorbed following oral administration and maximal plasma concentrations are obtained after approximately 4.5 hours. When the product is used according to the recommended dosage regime, steady state concentrations of meloxicam in plasma are reached on the second day of treatment.

Distribution

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

Metabolism

Meloxicam is predominantly found in plasma and is also a major biliary excretion product whereas urine contains only traces of the parent compound. Meloxicam is metabolised to an alcohol, an acid

derivative and to several polar metabolites. All major metabolites have been shown to be pharmacologically inactive.

Elimination

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium benzoate
Sorbitol
Glycerol
Polysorbate 80
Disodium phosphate dodecahydrate
Silica, colloidal anhydrous
Hydroxyethylcellulose
Citric acid monohydrate
Sodium cyclamate
Sucralose
Anise aroma
Water, purified

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 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

Polyethylene bottle containing 10 ml, 25 ml, 50 ml or 125 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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

CP-Pharma Handelsgesellschaft mbH
Ostlandring 13
D-31303 Burgdorf
Germany

8. 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)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21/02/2011
Date of last renewal: 07/01/2016

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

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:

Active substance:

Meloxicam 0.5 mg

Excipient:

Sodium benzoate 1.75 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension.

Yellow/green suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cats and guinea pigs

4.2 Indications for use, specifying the 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 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.

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

Do not use in cats less than 6 weeks of age.

Do not use in guinea pigs less than 4 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 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.

Melosus 0.5 mg/ml oral suspension for cats 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.

4.6 Adverse reactions (frequency and seriousness)

In cats, typical adverse reactions of 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.

These adverse reactions 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. Do not use in pregnant or lactating animals (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. Melosus 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 pharmacokinetic properties of the products used previously.

4.9 Amounts to be administered and administration route

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 Melosus 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.

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 therapy on the first day, twice 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-hour 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 Melosus oral suspension 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 Melosus according to the bodyweight of the guinea pig. Administer Melosus

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.

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.

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.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiinflammatory and antirheumatic products, non-steroids (oxicams)
ATC vet 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

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium benzoate
Sorbitol
Glycerol
Polysorbate 80
Disodium phosphate dodecahydrate
Silica, colloidal anhydrous
Hydroxyethylcellulose
Citric acid monohydrate
Sodium cyclamate
Sucralose
Anise aroma
Water, purified

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 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

Polyethylene bottle containing 5 ml, 10 ml or 25 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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

CP-Pharma Handelsgesellschaft mbH
Ostlandring 13

D-31303 Burgdorf
Germany

8. MARKETING AUTHORISATION NUMBERS

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

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21/02/2011
Date of last renewal: 07/01/2016

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 AND USE**
- C. STATEMENT OF THE MRLs**

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

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

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

Not applicable.

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Melosus 1.5 mg/ml oral suspension for dogs
meloxicam

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Meloxicam 1.5 mg

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

10 ml
25 ml
50 ml
125 ml

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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

CP-Pharma Handelsgesellschaft mbH
Ostlandring 13
D-31303 Burgdorf
Germany

16. 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

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Melosus 1.5 mg/ml oral suspension for dogs
meloxicam

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 1.5 mg/ml

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

10 ml
25 ml
50 ml

4. ROUTE(S) OF ADMINISTRATION

Oral use
Shake well before use.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Use by ...

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Melosus 1.5 mg/ml oral suspension for dogs
meloxicam

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 1.5 mg/ml

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

125 ml

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Shake well before 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}
Use by ...

11. SPECIAL STORAGE CONDITIONS

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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.

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

CP-Pharma Handelsgesellschaft mbH, Germany

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/10/116/003 125 ml

17. MANUFACTURER’S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Meloxicam 0.5 mg

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

5 ml
10 ml
25 ml

5. TARGET SPECIES

Cats and guinea pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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

CP-Pharma Handelsgesellschaft mbH
Ostlandring 13
D-31303 Burgdorf
Germany

16. MARKETING AUTHORISATION NUMBERS

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

17. MANUFACTURER’S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 0.5 mg/ml

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

5 ml
10 ml
25 ml

4. ROUTE OF ADMINISTRATION

Oral use.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Use by ...

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Melosus 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:

CP-Pharma Handelsgesellschaft mbH
Ostlandring 13
D-31303 Burgdorf
Germany

Manufacturer responsible for batch release:

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Melosus 1.5 mg/ml oral suspension for dogs
Meloxicam

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

Active substance:

Meloxicam 1.5 mg/ml

Excipients:

Sodium benzoate 1.75 mg/ml

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 dogs suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

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, 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 adverse reactions 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 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

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 Melosus 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 Melosus 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.

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

Shelf life after first opening the container: 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.

This 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 for cats should be used.

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. Melosus must not be administered in conjunction with other NSAIDs or glucocorticosteroids.

Incompatibilities:

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 case of overdose symptomatic treatment should be initiated.

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.

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

Medicines should not be disposed of via wastewater or household waste.
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 product is available on the website of the European Medicines Agency <http://www.ema.europa.eu/>.

15. OTHER INFORMATION

10, 25, 50 or 125 ml bottle.
Not all pack sizes may be marketed.

PACKAGE LEAFLET:

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

CP-Pharma Handelsgesellschaft mbH
Ostlandring 13
D-31303 Burgdorf
Germany

Manufacturer responsible for batch release:

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

Active substance:

Meloxicam 0.5 mg/ml

Excipients:

Sodium benzoate 1.75 mg/ml

4. INDICATION(S)

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

Do not use in cats less than 6 weeks of age.
Do not use in guinea pigs less than 4 weeks of age.

6. ADVERSE REACTIONS

In cats, 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.

These adverse reactions 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 during)
- 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 and guinea pigs

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

Oral use.

To be administered orally 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 Melosus 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.

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 Melosus 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.

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 syringes 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 Melosus oral suspension 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 Melosus according to the bodyweight of the guinea pig. Administer Melosus 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 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 bottle after EXP. The expiry date refers to the last day of that month.

Shelf-life after first opening the container: 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 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 veterinarian.

Melosus should not be used following parenteral injection of meloxicam or any other NSAIDs as appropriate dosage regimens for such follow-up treatments have not been established in cats.

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

Incompatibilities:

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 6 "Adverse reactions", are expected to be more severe and more frequent. In the 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.

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.

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

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

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<http://www.ema.europa.eu/>.

15. OTHER INFORMATION

5, 10 or 25 ml bottle.
Not all pack sizes may be marketed.