ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxivet 0.5 mg/ml oral suspension for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains

Active substance:

Meloxicam 0.5 mg

Excipient:

Sodium benzoate 1 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension. White to yellowish opaque 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 dogs.
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 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 dog, 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)

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, haematemisis, 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 the veterinarian should be sought.

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

Pre- treatment with anti-inflammatory substances may result in additional or increased adverse reactions 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 veterinary medicinal products used previously.

4.9 Amounts to be administered and administration route

Oral use.
Shake well before use.
To be administered 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 (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 has to be given with the 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.
For longer term treatment once clinical response has been observed (after 4 or more days), the dose of Meloxivet 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.

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: Anti-inflammatory 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
Meloxicam is completely absorbed following oral administration and maximal plasma concentrations are obtained after approximately 6.1 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 of meloxicam 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 1/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 of meloxicam is eliminated via faeces and the remainder via urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose
Xxanthan gum
Carboxymethylcellulose
Sodium benzoate
Sodium saccharinate

Glycerol
Sorbitol
Citric acid monohydrate
Sodium hydroxide
Purified water

6.2 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

10 ml: amber glass bottle (type III) with polyethylene child resistant closure, polyethylene insert and amber polypropylene dosing syringe.
30 ml: amber glass bottle (type III) with polypropylene child resistant closure, polyethylene insert and amber polypropylene dosing 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

Eli Lilly and Company Limited
Elanco Animal Health
Lilly House, Priestley Road
Basingstoke
Hampshire RG24 9NL
United Kingdom

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/07/077/001
EU/2/07/077/002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14.11.2007
Date of last renewal:

10. DATE OF REVISION OF THE TEXT

Detailed information on this 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

Meloxivet 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 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension. White to yellowish opaque 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 dogs.
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 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 dog, 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)

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, haematemisis, 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 the veterinarian should be sought.

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. Meloxivet must not be administered in conjunction with other NSAIDs or glucocorticosteroids.
Pre- treatment with anti-inflammatory substances may result in additional or increased adverse reactions 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 veterinary medicinal products used previously.

4.9 Amounts to be administered and administration route

Oral use.
Shake well before use.
To be administered 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 (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 has to be given with the measuring syringes provided in the package of the 30 ml and 150 ml pack size or with one of the two measuring syringes provided in the package of the 10 ml pack size. 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.

The suspension of the 10 ml pack size could be administered using the smallest syringe for dogs less than 8 kg body weight (one graduation corresponding to 0.5 kg of body weight) or the largest syringe for dogs over than 8 kg body weight (one graduation corresponding to 2.0 kg of body weight).

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.
For longer term treatment once clinical response has been observed (after 4 or more days), the dose of Meloxivet 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.
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: Anti-inflammatory 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
Meloxicam is completely absorbed following oral administration and maximal plasma concentrations are obtained after approximately 6.1 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 of meloxicam 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 1/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 of meloxicam is eliminated via faeces and the remainder via urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose
Xanthan gum
Carboxymethylcellulose
Sodium benzoate
Sodium saccharinate
Glycerol
Sorbitol
Citric acid monohydrate
Sodium hydroxide
Purified water

6.2 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

10 ml presentation: amber glass bottle (type III) with polyethylene child resistant closure, polyethylene insert and clear polypropylene dosing syringe. Two measuring syringes are provided.
30 ml and 150 ml presentation: amber glass bottle (type III) with polypropylene child resistant closure, polyethylene insert and clear polypropylene dosing 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

Eli Lilly and Company Limited
Elanco Animal Health
Lilly House, Priestley Road
Basingstoke
Hampshire RG24 9NL
United Kingdom

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/07/077/003
EU/2/07/077/004
EU/2/07/077/005

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14.11.2007
Date of last renewal:

10. DATE OF REVISION OF THE TEXT

Detailed information on this 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. MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO SAFE AND EFFECTIVE USE

D. STATEMENT OF THE MRLs

A. MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer(s) responsible for batch release

Lusomedicamenta S.A.
Estrada Consiglieri Pedroso, 69 B Queluz de Baixo
2730-055 Barcarena
Portugal

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

To be supplied only on veterinary prescription.

C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE PRODUCT

Not applicable.

D. STATEMENT OF THE MRLs

Not applicable.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box for bottle 10 and 30 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxivet 0.5 mg/ml oral suspension for dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Meloxicam	0.5 mg
Sodium benzoate	1 mg

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

10 ml
30 ml

5. TARGET SPECIES

Dogs

6. INDICATION(S)

Acute and chronic musculo-skeletal disorders.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in pregnant or lactating dogs

10. EXPIRY DATE

EXP
Once opened, use within 6 months.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eli Lilly and Company Limited
Elanco Animal Health
Lilly House, Priestley Road
Basingstoke
Hampshire RG24 9NL
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/07/077/001 10 ml
EU/2/07/077/002 30 ml

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label bottle 10 and 30 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxivet 0.5 mg/ml oral suspension for dogs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 0.5 mg/ml

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

10 ml
30 ml

4. ROUTE(S) OF ADMINISTRATION

Oral use.
To be administered with food.

5. WITHDRAWAL PERIOD

Not applicable.

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP
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 box for bottle 10, 30 and 150 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxivet 1.5 mg/ml oral suspension for dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Meloxicam	1.5 mg
Sodium benzoate	1 mg

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

10 ml
30 ml
150 ml

5. TARGET SPECIES

Dogs

6. INDICATION(S)

Acute and chronic musculo-skeletal disorders.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in pregnant or lactating dogs

10. EXPIRY DATE

EXP
Once opened, use within 6 months.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eli Lilly and Company Limited
Elanco Animal Health
Lilly House, Priestley Road
Basingstoke
Hampshire RG24 9NL
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/07/077/003	10 ml
EU/2/07/077/004	30 ml
EU/2/07/077/005	150 ml

17. MANUFACTURER'S BATCH NUMBER

Lot

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label bottle 150 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxivet 1.5 mg/ml oral suspension for dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Meloxicam	1.5 mg
Sodium benzoate	1 mg

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

150 ml

5. TARGET SPECIES

Dogs

6. INDICATION(S)

Acute and chronic musculo-skeletal disorders.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in pregnant or lactating dogs

10. EXPIRY DATE

EXP
Once opened, use within 6 months.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eli Lilly and Company Limited
Elanco Animal Health
Lilly House, Priestley Road
Basingstoke
Hampshire RG24 9NL
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/07/077/005

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label bottle 10 and 30 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxivet 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

10 ml
30 ml

4. ROUTE(S) OF ADMINISTRATION

Oral use.

5. WITHDRAWAL PERIOD

Not applicable.

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP
Once opened, use within 6 months.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

Meloxivet 0.5 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:
Eli Lilly and Company Limited
Elanco Animal Health
Lilly House, Priestley Road
Basingstoke
Hampshire RG24 9NL
United Kingdom

Manufacturer for the batch release:
Lusomedicamenta S.A.
Estrada Consiglieri Pedroso, 69 B Queluz de Baixo
2730-055 Barcarena
Portugal

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxivet 0.5 mg/ml oral suspension for dogs

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

One ml contains:

Meloxicam	0.5 mg
Sodium benzoate	1 mg

4. INDICATION(S)

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

5. CONTRAINDICATIONS

Do not administer Meloxivet:
- if your dog is pregnant or during lactation
- if your dog is suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders
- if your dog is hypersensitive (allergic) to the active substance or to any of the other ingredients.
- if your dogs is 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.

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 haemorrhagic diarrhoea, haematemisis, gastrointestinal ulceration and elevated liver enzymes have been reported.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

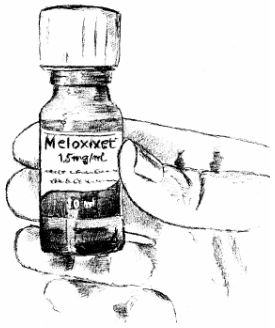
Dogs.

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

Oral use. To be administered with food .
The suspension has to be given with the 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.

Dosage
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 (24 hour intervals) at a maintenance dose of 0.1 mg meloxicam/kg body weight.

Route and method of administration



Shake bottle well. Push down and unscrew bottle top. Attach the dosing syringe to the bottle by gently pushing the end onto the top the bottle

Turn the bottle syringe upside down. Pull the plunger out until the black on the plunger corresponds to your dog's bodyweight in kilograms.

Turn the bottle right way up and with a twisting movement separate the dosing syringe from the bottle.

By pushing the plunger in empty the contents of the syringe onto the food.

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.
For longer term treatment once clinical response has been observed (after 4 or more days), the dose of Meloxivet 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.
Avoid introduction of contamination during use.

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

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
This veterinary medicinal product does not require any special storage conditions.
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.
Do not use after the expiry date stated on the label and carton after EXP.
Shelf life after first opening the container: 6 months.

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 dog, as there is a potential risk of increased renal toxicity.
Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects. Meloxivet 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.
In the case of overdose 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 MATERIALS, IF ANY

Any unused veterinary medicinal product or waste material 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 product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

15. OTHER INFORMATION

10 ml presentation: amber glass bottle (type III) with polyethylene child resistant closure, polyethylene insert and an amber polypropylenedosing syringe.
30 ml presentation: amber glass bottle (type III) with polypropylene child resistant closure, polyethylene insert and an amber polypropylene dosing syringe.

Not all pack sizes may be marketed.

PACKAGE LEAFLET FOR:

Meloxivet 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:
Eli Lilly and Company Limited
Elanco Animal Health
Lilly House, Priestley Road
Basingstoke
Hampshire RG24 9NL
United Kingdom

Manufacturer for the batch release:
Lusomedicamenta S.A.
Estrada Consiglieri Pedroso, 69 B Queluz de Baixo
2730-055 Barcarena
Portugal

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxivet 1.5 mg/ml oral suspension for dogs

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

One ml contains:

Meloxicam	1.5 mg
Sodium benzoate	1 mg

4. INDICATION(S)

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

5. CONTRAINDICATIONS

Do not administer Meloxivet:
- if your dog is pregnant or during lactation
- if your dog is suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders
- if your dog is hypersensitive (allergic) to the active substance or to any of the other ingredients.
- if your dogs is 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.

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 haemorrhagic diarrhoea, haematemisis, gastrointestinal ulceration and elevated liver enzymes have been reported.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

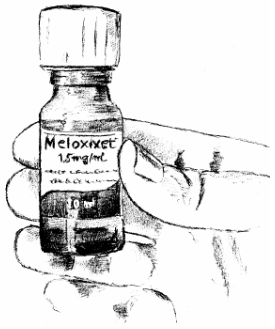
Dogs.

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

Oral use. To be administered with food.
The suspension has to be given with the measuring syringe provided in the package of the 30 and 150 ml pack size or with one of the two measuring syringes provided in the package of the 10 ml pack size. 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.

Dosage
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 (24 hour intervals) at a maintenance dose of 0.1 mg meloxicam/kg body weight.

Route and method of administration



Shake bottle well. Push down and unscrew bottle top. Attach the dosing syringe to the bottle by gently pushing the end onto the top the bottle

Turn the bottle syringe upside down. Pull the plunger out until the black on the plunger corresponds to your dog's bodyweight in kilograms.

Turn the bottle right way up and with a twisting movement separate the dosing syringe from the bottle.

By pushing the plunger in empty the contents of the syringe onto the food.

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.
For longer term treatment once clinical response has been observed (after 4 or more days), the dose of Meloxivet 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.
Avoid introduction of contamination during use.

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.
The suspension of the 10 ml pack size could be administered using the smallest syringe for dogs less than 8 kg body weight (one graduation corresponding to 0.5 kg of body weight) or the largest syringe for dogs over than 8 kg body weight (one graduation corresponding to 2.0 kg of body weight).

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
This veterinary medicinal product does not require any special storage conditions.
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.
Do not use after the expiry date stated on the label and carton after EXP.
Shelf life after first opening the container: 6 months.

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 dog, as there is a potential risk of increased renal toxicity.
Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects. Meloxivet 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.
In the case of overdose 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 MATERIALS, IF ANY

Any unused veterinary medicinal product or waste material 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 product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

15. OTHER INFORMATION

10 ml presentation: amber glass bottle (type III) with polyethylene child resistant closure, polyethylene insert and clear polypropylene dosing syringe. Two measuring syringes are provided.
30 ml and 150 ml presentation: amber glass bottle (type III) with polypropylene child resistant closure, polyethylene insert and clear polypropylene dosing syringe.

Not all pack sizes may be marketed.