1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxidolor 5 mg/ml solution for injection for dogs, cats, cattle and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:

Active substance:  
Meloxicam 5 mg

Excipient:  
Ethanol 150 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.  
Clear yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs, cats, cattle (calves and young cattle) and pigs

4.2 Indications for use, specifying the target species

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

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

Cattle:  
For use in acute respiratory infection with appropriate antibiotic therapy to reduce clinical signs in cattle.  
For use in diarrhoea in combination with oral re-hydration therapy to reduce clinical signs in calves of over one week of age and young, non-lactating cattle.  
For the relief of post-operative pain following dehorning in calves.

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

4.3 Contraindications

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

Do not use in dogs and cats suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.

Do not use in dogs and cats less than 6 weeks of age nor in cats of less than 2 kg.
Do not use in pregnant or lactating dogs and cats.

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

4.4 Special warnings for each target species

Treatment of piglets with Meloxidolor before castration reduces post-operative pain.
To obtain pain relief for cattle and pigs during surgery co-medication with an appropriate anaesthetic/sedative is needed.
To obtain the best possible pain relieving effect for pigs post-surgery Meloxidolor should be administered 30 minutes before surgical intervention.

4.5 Special precautions for use

Special precautions for use in animals

Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of renal toxicity. During anaesthesia, monitoring and fluid therapy should be considered as standard practice. Any oral follow-up therapy using meloxicam or other Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) should not be administered in cats, as appropriate dosage regimens for such follow-up treatments have not been established.

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

Accidental self-injection may give rise to pain. People with known hypersensitivity to NSAIDs should avoid contact with the veterinary medicinal product.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Meloxicam may be harmful for the foetus and unborn child. Pregnant women and women of child-bearing potential should not administer this product.

4.6 Adverse reactions (frequency and seriousness)

For dogs and cats:
Typical adverse reactions of NSAIDs such as loss of appetite, vomiting, diarrhoea, faecal occult blood, lethargy and renal failure have occasionally been reported. In very rare cases elevated liver enzymes have been reported.
In dogs, in very rare cases, haemorrhagic diarrhoea, haematemesis and gastrointestinal ulceration have been reported.
In dogs, these side effects occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.

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

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

For cattle and pigs:
Subcutaneous, intramuscular as well as intravenous administration is well tolerated; only a slight transient swelling at the injection site following subcutaneous administration was observed in less than 10 % of the cattle treated in clinical studies.
In very rare cases anaphylactic reactions, which may be serious (including fatal), may occur and should be treated symptomatically.

4.7 Use during pregnancy, lactation or lay

**Dogs and cats:** The safety of the veterinary medicinal product has not been established during pregnancy and lactation (See section 4.3).

**Cattle:** Can be used during pregnancy.

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

4.8 Interaction with other medicinal products and other forms of interaction

For dogs and cats:
Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects. Meloxidolor must not be administered in conjunction with other NSAIDs or glucocorticosteroids. Concurrent administration of potential nephrotoxic drugs should be avoided. In animals at anaesthetic risk (e.g. aged animals) intravenous or subcutaneous fluid therapy during anaesthesia should be taken into consideration. When anaesthesia and NSAID are concomitantly administered, a risk for renal function cannot be excluded.

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

For cattle and pigs:
Do not administer concurrently with glucocorticosteroids, other non-steroidal anti-inflammatory drugs or with anticoagulant agents.

4.9 Amounts to be administered and administration route

**Dogs:**
Musculo-skeletal disorders:
Single subcutaneous injection at a dosage of 0.2 mg meloxicam/kg body weight (i.e. 0.4 ml/10 kg body weight).
Oral suspensions of meloxicam for dogs may be used for continuation of treatment at a dosage of 0.1 mg meloxicam/kg body weight, 24 hours after administration of the injection.

Reduction of post-operative pain (over a period of 24 hours):
Single intravenous or subcutaneous injection at a dosage of 0.2 mg meloxicam/kg body weight (i.e. 0.4 ml/10 kg body weight) before surgery, for example at the time of induction of anaesthesia.

**Cats:**
Reduction of post-operative pain:
Single subcutaneous injection at a dosage of 0.3 mg meloxicam/kg body weight (i.e. 0.06 ml/kg body weight) before surgery, for example at the time of induction of anaesthesia.

**Cattle:**
Single subcutaneous or intravenous injection at a dosage of 0.5 mg meloxicam/kg body weight (i.e.10. 0 ml/100 kg body weight) in combination with antibiotic therapy or with oral re-hydration therapy, as appropriate.

**Pigs:**
Locomotor disorders:
Single intramuscular injection at a dosage of 0.4 mg meloxicam/kg body weight (i.e. 2.0 ml/25 kg body weight). If required, a second administration of meloxicam can be given after 24 hours.
Reduction of post-operative pain:
Single intramuscular injection at a dosage of 0.4 mg meloxicam/kg body weight (i.e. 0.4 ml/5 kg body weight) before surgery.

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

Avoid introduction of contamination during use. The stopper should not be punctured more than 20 times.

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

In case of overdose symptomatic treatment should be initiated.

4.11 Withdrawal periods

Cattle: Meat and offal: 15 days
Pigs: Meat and offal: 5 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiinflammatory and antirheumatic products, non-steroids (oxicams)
ATCvet code: QM01AC06

5.1 Pharmacodynamic properties

Meloxicam is a Non-Steroidal Anti-Inflammatory Drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, analgesic, anti-exudative, analgesic 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). Meloxicam also has anti-endotoxic properties because it has been shown to inhibit production of thromboxane B₂ induced by E. coli endotoxin administration in calves and pigs.

5.2 Pharmacokinetic particulars

Absorption
Following subcutaneous administration, meloxicam is completely bioavailable and maximal mean plasma concentrations of 0.73 μg/ml in dogs and 1.1 μg/ml in cats were reached approximately 2.5 hours and 1.5 hours post administration, respectively. After a single subcutaneous dose of 0.5 mg meloxicam/kg, C_max values of 2.1 μg/ml were reached after 7.7 hours in young cattle. Following single intramuscular doses of 0.4 mg meloxicam/kg, a C_max value of 1.1 to 1.5 μg/ml was reached within 1 hour in pigs.

Distribution
There is a linear relationship between the dose administered and plasma concentration observed in the therapeutic dose range in dogs and cats. More than 97 % of meloxicam is bound to plasma proteins. The volume of distribution is 0.3 l/kg in dogs and 0.09 l/kg in cats. In cattle and pigs, the highest meloxicam concentrations are to be found in liver and kidney. Comparatively low concentrations are detectable in skeletal muscle and fat.

Metabolism
Meloxicam is predominantly found in plasma. For dogs, cats and cattle it is also a major biliary excretion product whereas urine contains only traces of the parent compound. In cattle, meloxicam is also a major excretion product in milk. In pigs, bile and urine contain only traces of the parent compound. Five major metabolites were detected all having been shown to be pharmacologically inactive. Meloxicam is metabolised to an alcohol, an acid derivative and to several polar metabolites. The main pathway of meloxicam biotransformation is oxidation.

Elimination
In dogs and cats, Meloxicam is eliminated with a half-life of 24 hours. Approximately 75 % of the administered dose is eliminated via faeces and the remainder via urine in dogs. In cats, the detection of metabolites from the parent compound in urine and faeces, but not in plasma is indicative for their rapid excretion. 21 % of the recovered dose is eliminated in urine (2 % as unchanged meloxicam, 19 % as metabolites) and 79 % in the faeces (49 % as unchanged meloxicam, 30 % as metabolites). Meloxicam is eliminated with a half-life of 26 hours after subcutaneous injection in young cattle. In pigs, after intramuscular administration, the mean plasma elimination half-life is approximately 2.5 hours. Approximately 50 % of the administered dose is eliminated via urine and the remainder via faeces.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol
Poloxamer 188
Sodium chloride
Glycine
Sodium hydroxide
Hydrochloric acid
Glycofurol
Meglumine
Water for injections

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years. Shelf-life after first opening the immediate packaging: 4 weeks.

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

Colourless type I glass vials of 10 ml, 20 ml or 100 ml, closed with a rubber stopper and sealed with an aluminium cap.

Not all pack sizes may be marketed.
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

Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands
Tel: +31 (0)348 565858
Fax: +31 (0)348 565454
E-mail: info@levetpharma.com

8. MARKETING AUTHORISATION NUMBERS

EU/2/13/148/001
EU/2/13/148/002
EU/2/13/148/003

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22/04/2013

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

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:

**Active substance:**
Meloxicam  20 mg

**Excipient:**
Ethanol    150 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, pigs and horses

4.2 Indications for use, specifying the target species

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

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

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

4.3 Contraindications

See also section 4.7.
Do not use in horses less than 6 weeks of age.
Do not use in animals suffering from impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of ulcerogenic gastrointestinal lesions.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
For the treatment of diarrhoea in cattle, do not use in animals of less than one week of age.

4.4 Special warnings

None.

4.5 Special precautions for use

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

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Accidental self-injection may give rise to pain. People with known hypersensitivity to Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) should avoid contact with the veterinary medicinal product.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Meloxicam may be harmful for the foetus and unborn child. Pregnant women and women of childbearing potential should not administer this product.

4.6 Adverse reactions (frequency and seriousness)

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

In horses, a transient swelling at the injection site can occur but resolves without intervention.

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

4.7 Use during pregnancy, lactation or lay

Cattle and pigs: Can be used during pregnancy and lactation.
Horses: Do not use in pregnant or lactating mares.

See also section 4.3.

4.8 Interaction with other medicinal products and other forms of interaction

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

4.9 Amounts to be administered and administration route

Cattle:
Single subcutaneous or intravenous injection at a dosage of 0.5 mg meloxicam/kg body weight (i.e. 2.5 ml/100 kg body weight) in combination with antibiotic therapy or with oral re-hydration therapy, as appropriate.
**Pigs:**
Single intramuscular injection at a dosage of 0.4 mg meloxicam/kg body weight (i.e. 2.0 ml/100 kg body weight) in combination with antibiotic therapy, as appropriate. If required, a second administration of meloxicam can be given after 24 hours.

**Horses:**
Single intravenous injection at a dosage of 0.6 mg meloxicam/kg body weight (i.e. 3.0 ml/100 kg body weight).

Avoid introduction of contamination during use. The stopper should not be punctured more than 20 times.

**4.10 Overdose (symptoms, emergency procedures, antidotes if necessary)**
In case of overdose symptomatic treatment should be initiated.

**4.11 Withdrawal periods**

<table>
<thead>
<tr>
<th>Cattle</th>
<th>Meat and offal: 15 days; Milk: 5 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pigs</td>
<td>Meat and offal: 5 days</td>
</tr>
<tr>
<td>Horses</td>
<td>Meat and offal: 5 days.</td>
</tr>
</tbody>
</table>

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

5. **PHARMACOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Antiinflammatory and antirheumatic products, non-steroids (oxicams).
ATCvet code: QM01AC06

**5.1 Pharmacodynamic properties**

Meloxicam is a Non-Steroidal Anti-Inflammatory Drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, anti-exudative, analgesic and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it also inhibits collagen-induced thrombocyte aggregation. Meloxicam also has anti-endotoxic properties because it has been shown to inhibit production of thromboxane B₂ induced by *E. coli* endotoxin administration in calves, lactating cows and pigs.

**5.2 Pharmacokinetic particulars**

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

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

**Metabolism**
Meloxicam is predominantly found in plasma. In cattle, meloxicam is also a major excretion product in milk and bile whereas urine contains only traces of the parent compound. In pigs, bile and urine contain only traces of the parent compound. Meloxicam is metabolised to an alcohol, an acid derivative and to several polar metabolites. All major metabolites have been shown to be...
pharmacologically inactive. The metabolism in horses has not been investigated.

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

6. **PHARMACEUTICAL PARTICULARS**

6.1 **List of excipients**

Ethanol
Poloxamer 188
Macrogol 300
Glycine
Disodium edetate
Sodium hydroxide
Hydrochloric acid
Meglumine
Water for injections

6.2 **Incompatibilities**

None known.

6.3 **Shelf life**

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years. Shelf-life after first opening the immediate packaging: 4 weeks.

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**

Colourless type I glass vial containing 50 ml or 100 ml, closed with a rubber stopper and sealed with an aluminium cap. Not all pack sizes may be marketed.

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

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

7. **MARKETING AUTHORISATION HOLDER**

Le Vet Beheer B.V. Wilgenweg 7
3421 TV Oudewater
The Netherlands
tel: +31 (0)348 565858
8. MARKETING AUTHORISATION NUMBER(S)

EU/2/13/148/004
EU/2/13/148/005

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22/04/2013

10. DATE OF REVISION OF THE TEXT


PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.
1. NAME OF THE VETERINARY MEDICINAL PRODUCT
Meloxidolor 40 mg/ml solution for injection for cattle and horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
One ml contains:

Active substance:
Meloxicam 40 mg

Excipient:
Ethanol 150 mg
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Solution for injection.
Clear yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species
Cattle and horses

4.2 Indications for use, specifying the target species

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

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

4.3 Contraindications
See also section 4.7.
Do not use in horses less than 6 weeks of age.
Do not use in animals suffering from impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of ulcerogenic gastrointestinal lesions.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
For the treatment of diarrhoea in cattle, do not use in animals of less than one week of age.

4.4 Special warnings
None.
4.5 Special precautions for use

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

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Accidental self-injection may give rise to pain. People with known hypersensitivity to Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) should avoid contact with the veterinary medicinal product.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Meloxicam may be harmful for the foetus and unborn child. Pregnant women and women of child-bearing potential should not administer this product.

4.6 Adverse reactions (frequency and seriousness)
In cattle intravenous administration is well tolerated.
In horses, a transient swelling at the injection site can occur but resolves without intervention.
In very rare cases anaphylactoid reactions, which may be serious (including fatal), may occur and should be treated symptomatically.

4.7 Use during pregnancy, lactation or lay
Cattle: Can be used during pregnancy and lactation.
Horses: Do not use in pregnant or lactating mares.
See also section 4.3.

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

4.9 Amounts to be administered and administration route
Cattle:
Single intravenous injection at a dosage of 0.5 mg meloxicam/kg body weight (i.e. 1.25 ml/100 kg body weight) in combination with antibiotic therapy or with oral re-hydration therapy, as appropriate.

Horses:
Single intravenous injection at a dosage of 0.6 mg meloxicam/kg body weight (i.e. 1.5 ml/100 kg body weight).

Avoid introduction of contamination during use. The stopper should not be punctured more than 20 times.

4.10 Overdose (symptoms, emergency procedures, antidotes if necessary)
In case of overdose symptomatic treatment should be initiated.
4.11 Withdrawal period(s)

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

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiinflammatory and antirheumatic products, non-steroids (oxicams).
ATCvet code: QM01AC06

5.1 Pharmacodynamic properties

Meloxicam is a Non-Steroidal Anti-Inflammatory Drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, anti-exudative, analgesic and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it also inhibits collagen-induced thrombocyte aggregation. Meloxicam also has anti-endotoxic properties because it has been shown to inhibit production of thromboxane B₂ induced by E. coli endotoxin administration in calves and lactating cows.

5.2 Pharmacokinetic particulars

Absorption
No data available for intravenous administration in cattle and horses.

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

Metabolism
Meloxicam is predominantly found in plasma. In cattle, meloxicam is also a major excretion product in milk and bile whereas urine contains only traces of the parent compound. Meloxicam is metabolised to an alcohol, an acid derivative and to several polar metabolites. All major metabolites have been shown to be pharmacologically inactive. The metabolism in horses has not been investigated.

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol
Poloxamer 188
Macrogol 300
Glycine
Disodium edetate
Sodium hydroxide
Hydrochloric acid
Meglumine
Water for injections

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years. Shelf-life after first opening the immediate packaging: 4 weeks.

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

Colourless type I glass vial containing 50 ml or 100 ml, closed with a rubber stopper and sealed with an aluminium cap. Not all pack sizes may be marketed.

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

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

7. MARKETING AUTHORISATION HOLDER

Le Vet Beheer B.V. Wilgenweg 7
3421 TV Oudewater
The Netherlands
tel: +31 (0)348 565858
fax: +31 (0)348 565454
e-mail: info@levetpharma.com

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/13/148/006
EU/2/13/148/007

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22/04/2013

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 OF THE MARKETING AUTHORISATION REGARDING SUPPLY AND USE

To be supplied only on veterinary prescription.

C. STATEMENT OF THE MRLs

The active substance in Meloxidolor is an allowed substance as described in table 1 of the annex to Commission Regulation (EU) No 37/2010:

<table>
<thead>
<tr>
<th>Pharmacologically active substance</th>
<th>Marker residue</th>
<th>Animal species</th>
<th>MRL</th>
<th>Target tissues</th>
<th>Other provisions</th>
<th>Therapeutic classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meloxicam</td>
<td>Meloxicam</td>
<td>Bovine, caprine, porcine, rabbit, Equidae</td>
<td>20 μg/kg</td>
<td>Muscle, Liver, Kidney</td>
<td>NO ENTRY</td>
<td>Anti-inflammatory agents/Non steroidal anti-inflammatory agents</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bovine, caprine</td>
<td>15 μg/kg</td>
<td>Milk</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

LABELLING AND PACKAGE LEAFLET
A. LABELLING
PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

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

{Label for 100 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxidolor 5 mg/ml solution for injection for dogs, cats, cattle and pigs
Meloxicam

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Meloxicam 5 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

10 ml
20 ml
100 ml

5. TARGET SPECIES

Dogs, cats, cattle (calves and young cattle) and pigs

6. INDICATION(S)

Read the package leaflet before use

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use

8. WITHDRAWAL PERIOD

Withdrawal period:
Cattle: Meat and offal: 15 days
Pigs: Meat and offal: 5 days
9. **SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

10. **EXPIRY DATE**

EXP (month/year)
Once broached, use by….

11. **SPECIAL STORAGE CONDITIONS**

Read the package leaflet before use.

12. **SPECIAL 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. 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**

Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

16. **MARKETING AUTHORISATION NUMBER(S)**

EU/2/13/148/001
EU/2/13/148/002
EU/2/13/148/003

17. **MANUFACTURER’S BATCH NUMBER**

Batch {number}
MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Label for 10 ml and 20 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxidolor 5 mg/ml solution for injection for dogs, cats, cattle and pigs
Meloxicam

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 5 mg/ml

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

10 ml
20 ml

4. ROUTE(S) OF ADMINISTRATION

Cattle: SC, IV
Pigs: IM
Dogs: IV or SC
Cats: SC

5. WITHDRAWAL PERIOD

Withdrawal period:
Cattle: Meat and offal: 15 days
Pigs: Meat and offal: 5 days

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP (month/year)
Once broached, use by ….

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.
<table>
<thead>
<tr>
<th>PARTICULARS TO APPEAR ON THE OUTER PACKAGE</th>
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<tbody>
<tr>
<td>{Carton for 50 ml and 100 ml}</td>
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</table>

<table>
<thead>
<tr>
<th>1. NAME OF THE VETERINARY MEDICINAL PRODUCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meloxidolor 20 mg/ml solution for injection for cattle, pigs and horses</td>
</tr>
<tr>
<td>Meloxicam</td>
</tr>
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<table>
<thead>
<tr>
<th>2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES</th>
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<tbody>
<tr>
<td>Meloxicam 20 mg/ml</td>
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<tr>
<th>3. PHARMACEUTICAL FORM</th>
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</thead>
<tbody>
<tr>
<td>Solution for injection</td>
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</tbody>
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<table>
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<tr>
<th>4. PACKAGE SIZE(S)</th>
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</thead>
<tbody>
<tr>
<td>50 ml</td>
</tr>
<tr>
<td>100 ml</td>
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</table>

<table>
<thead>
<tr>
<th>5. TARGET SPECIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cattle, pigs and horses</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>6. INDICATION(S)</th>
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<tbody>
<tr>
<td>Read the package leaflet before use</td>
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<table>
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<tr>
<th>7. METHOD AND ROUTE(S) OF ADMINISTRATION</th>
</tr>
</thead>
<tbody>
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<td>Read the package leaflet before use.</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>8. WITHDRAWAL PERIOD</th>
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</thead>
<tbody>
<tr>
<td>Withdrawal period:</td>
</tr>
<tr>
<td><strong>Cattle</strong>: meat and offal: 15 days; milk: 5 days</td>
</tr>
<tr>
<td><strong>Pigs, horses</strong>: meat and offal: 5 days</td>
</tr>
<tr>
<td>Not authorised to use in horses producing milk for human consumption.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>9. SPECIAL WARNING(S), IF NECESSARY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Read the package leaflet before use</td>
</tr>
</tbody>
</table>
10. **EXPIRY DATE**

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

11. **SPECIAL STORAGE CONDITIONS**

   Read the package leaflet before use.

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. To be supplied only on veterinary prescription.

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

   Keep out of the sight and reach of children.

15. **NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

   Le Vet Beheer B.V.
   Wilgenweg 7
   3421 TV Oudewater
   The Netherlands

16. **MARKETING AUTHORISATION NUMBER(S)**

   EU/2/13/148/004
   EU/2/13/148/005

17. **MANUFACTURER'S BATCH NUMBER**

   Batch {number}
### PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

[Label for 100 ml]

### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

### 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Meloxicam 20 mg/ml

### 3. PHARMACEUTICAL FORM

Solution for injection

### 4. PACKAGE SIZES

100 ml

### 5. TARGET SPECIES

Cattle, pigs and horses

### 6. INDICATION(S)

Read the package leaflet before use.

### 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

### 8. WITHDRAWAL PERIOD

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

### 9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
10. **EXPIRY DATE**

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

11. **SPECIAL STORAGE CONDITIONS**

   Read the package leaflet before use.

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. To be supplied only on veterinary prescription.

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

   Keep out of the sight and reach of children

15. **NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

   Le Vet Beheer B.V.
   Wilgenweg 7
   3421 TV Oudewater
   The Netherlands

16. **MARKETING AUTHORISATION NUMBERS**

   EU/2/13/148/005

17. **MANUFACTURER'S BATCH NUMBER**

   Batch {number}
MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 20 mg/ml

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

50 ml

4. ROUTE(S) OF ADMINISTRATION

Cattle: SC or IV
Pigs: IM
Horses: IV

5. WITHDRAWAL PERIOD

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

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

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

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.
PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Carton for 50 ml and 100 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxidolor 40 mg/ml solution for injection for cattle and horses
Meloxicam

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Meloxicam 40 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE(S)

50 ml
100 ml

5. TARGET SPECIES

Cattle and horses

6. INDICATION(S)

Read the package leaflet before use

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet before use.

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. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/13/148/006
EU/2/13/148/007

17. MANUFACTURER’S BATCH NUMBER

Batch {number}
PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{Label for 100 ml}

1. **NAME OF THE VETERINARY MEDICINAL PRODUCT**

Meloxidolor 40 mg/ml solution for injection for cattle and horses
Meloxicam

2. **STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Meloxicam 40 mg/ml

3. **PHARMACEUTICAL FORM**

Solution for injection

4. **PACKAGE SIZE(S)**

100 ml

5. **TARGET SPECIES**

Cattle and horses

6. **INDICATION(S)**

Read the package leaflet before use.

7. **METHOD AND ROUTE(S) OF ADMINISTRATION**

Read the package leaflet before use.

8. **WITHDRAWAL PERIOD**

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

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

9. **SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.
10. **EXPIRY DATE**

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

11. **SPECIAL STORAGE CONDITIONS**

Read the package leaflet before use.

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. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children

15. **NAME AND ADDRESS OF THE MARKETING AUTHORIZATION HOLDER**

Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

16. **MARKETING AUTHORIZATION NUMBERS**

EU/2/13/148/007

17. **MANUFACTURER’S BATCH NUMBER**

Batch {number}
<table>
<thead>
<tr>
<th>MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. NAME OF THE VETERINARY MEDICINAL PRODUCT</strong></td>
</tr>
<tr>
<td>Meloxidolor 40 mg/ml solution for injection for cattle and horses</td>
</tr>
<tr>
<td>Meloxicam</td>
</tr>
<tr>
<td><strong>2. QUANTITY OF THE ACTIVE SUBSTANCE(S)</strong></td>
</tr>
<tr>
<td>Meloxicam 40 mg/ml</td>
</tr>
<tr>
<td><strong>3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES</strong></td>
</tr>
<tr>
<td>50 ml</td>
</tr>
<tr>
<td><strong>4. ROUTE(S) OF ADMINISTRATION</strong></td>
</tr>
<tr>
<td>Cattle: IV</td>
</tr>
<tr>
<td>Horses: IV</td>
</tr>
<tr>
<td><strong>5. WITHDRAWAL PERIOD</strong></td>
</tr>
<tr>
<td>Withdrawal period:</td>
</tr>
<tr>
<td>Cattle: meat and offal: 15 days; milk: 5 days</td>
</tr>
<tr>
<td>Horses: meat and offal: 5 days.</td>
</tr>
<tr>
<td>Not authorised to use in horses producing milk for human consumption.</td>
</tr>
<tr>
<td><strong>6. BATCH NUMBER</strong></td>
</tr>
<tr>
<td>Batch {number}</td>
</tr>
<tr>
<td><strong>7. EXPIRY DATE</strong></td>
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<tr>
<td>EXP {month/year}</td>
</tr>
<tr>
<td>Once broached, use by…</td>
</tr>
<tr>
<td><strong>8. THE WORDS &quot;FOR ANIMAL TREATMENT ONLY&quot;</strong></td>
</tr>
<tr>
<td>For animal treatment only.</td>
</tr>
</tbody>
</table>
B. PACKAGE LEAFLET
PACKAGE LEAFLET FOR:

Meloxidolor 5 mg/ml solution for injection for dogs, cats, cattle and pigs

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

Marketing authorisation holder:
Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

Manufacturer for the batch release:
Produlab Pharma B.V.
Forellenweg 16
4941 SJ Raamsdonksveer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxidolor 5 mg/ml solution for injection for dogs, cats, cattle and pigs
Meloxicam

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

One ml contains:

Active substance:
Meloxicam 5 mg

Excipient:
Ethanol 150 mg

4. INDICATION(S)

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

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

Cattle:
For use in acute respiratory infection with appropriate antibiotic therapy to reduce clinical signs in cattle.
For use in diarrhoea in combination with oral re-hydration therapy to reduce clinical signs in calves of over one week of age and young, non-lactating cattle.
For the relief of post-operative pain following dehorning in calves.

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

5. CONTRAINDICATIONS

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

Do not use in pregnant or lactating dogs and cats.
Do not use in dogs and cats suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in dog and cats less than 6 weeks of age nor in cats of less than 2 kg.

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

6. ADVERSE REACTIONS

For dogs and cats:
Typical adverse reactions of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) such as loss of appetite, vomiting, diarrhoea, faecal occult blood, lethargy and renal failure have occasionally been reported. In very rare cases elevated liver enzymes have been reported.

In dogs, in very rare cases, haemorrhagic diarrhoea, haematemesis and gastrointestinal ulceration have been reported.
In dogs, these side effects occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.

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

For cattle and pigs:
Subcutaneous, intramuscular as well as intravenous administration is well tolerated; only a slight transient swelling at the injection site following subcutaneous administration was observed in less than 10 % of the cattle treated in clinical studies.
In very rare cases anaphylactic reactions, which may be serious (including fatal), may occur and should be treated symptomatically.
If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

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

7. TARGET SPECIES

Dogs, cats, cattle (calves and young cattle) and pigs

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

Dosage for each species

Dogs:
Musculo-skeletal disorders:
Single subcutaneous injection at a dosage of 0.2 mg meloxicam/kg body weight (i.e. 0.4 ml/10 kg body weight).
Oral suspensions of meloxicam for dogs may be used for continuation of treatment at a dosage of 0.1 mg meloxicam/kg body weight, 24 hours after administration of the injection.
Reduction of post-operative pain (over a period of 24 hours):
Single intravenous or subcutaneous injection at a dosage of 0.2 mg meloxicam/kg body weight (i.e. 0.4 ml/10 kg body weight) before surgery, for example at the time of induction of anaesthesia.

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

Cattle:
Single subcutaneous or intravenous injection at a dosage of 0.5 mg meloxicam/kg body weight (i.e. 10.0 ml/100 kg body weight) in combination with antibiotic therapy or with oral re-hydration therapy, as appropriate.

Pigs:
Locomotor disorders:
Single intramuscular injection at a dosage of 0.4 mg meloxicam/kg body weight (i.e. 2.0 ml/25 kg body weight). If required, a second administration of meloxicam can be given after 24 hours.
Reduction of post-operative pain:
Single intramuscular injection at a dosage of 0.4 mg meloxicam/kg body weight (i.e. 0.4 ml/5 kg body weight) before surgery.

9. ADVICE ON CORRECT ADMINISTRATION
Particular care should be taken with regard to the accuracy of dosing including the use of an appropriate dosing device and careful estimation of body weight.
Avoid introduction of contamination during use. The stopper should not be punctured more than 20 times.
In case of overdose symptomatic treatment should be initiated.

10. WITHDRAWAL PERIOD
Cattle: meat and offal: 15 days
Pigs: meat and offal: 5 days

11. SPECIAL STORAGE PRECAUTIONS
Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Shelf-life after first opening the container: 4 weeks.
Do not use after the expiry date stated on the label after EXP.

12. SPECIAL WARNING(S)
Treatment of piglets with Meloxidolor before castration reduces post-operative pain. To obtain pain relief during surgery co-medication with an appropriate anaesthetic/sedative is needed.
To obtain the best possible pain relieving effect post-surgery Meloxidolor should be administered 30 minutes before surgical intervention.
Precautions for use in animals
If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.
Avoid use in any dehydrated, hypovolaemic or hypotensive animals, as there may be a potential risk of renal toxicity.
During anaesthesia, monitoring and fluid therapy should be considered as standard practice.
Any oral follow-up therapy using meloxicam or other NSAIDs should not be administered in cats, as appropriate dosage regimens for such follow-up treatments have not been established.

Precautions to be taken by the person administering the product
Accidental self-injection may give rise to pain. People with known hypersensitivity to NSAIDs should avoid contact with the veterinary medicinal product.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Meloxicam may be harmful for the foetus and unborn child. Pregnant women and women of child-bearing potential should not administer this product.

Use during pregnancy and lactation
Dogs and cats: The safety of the veterinary medicinal product has not been established during pregnancy and lactation.
Cattle: Can be used during pregnancy.
Pigs: Can be used during pregnancy and lactation.

Interactions
For dogs and cats:
Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects. Meloxidolor must not be administered in conjunction with other NSAIDs or glucocorticosteroids. Concurrent administration of potential nephrotoxic drugs should be avoided. In animals at anaesthetic risk (e.g. aged animals) intravenous or subcutaneous fluid therapy during anaesthesia should be taken into consideration. When anaesthesia and NSAID are concomitantly administered, a risk for renal function cannot be excluded.

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

For cattle and pigs:
Do not administer concurrently with glucocorticosteroids, other non-steroidal anti-inflammatory drugs or with anticoagulant agents.

Overdose
In case of overdose symptomatic treatment should be initiated.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION
**Package (size)**
Colourless type I glass vial of 10 ml, 20 ml or 100 ml, closed with a rubber stopper and sealed with an aluminium cap.

Not all pack sizes may be marketed.
PACKAGE LEAFLET FOR:

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

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

Marketing authorisation holder:
Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

Manufacturer for the batch release:
Produlab Pharma B.V.
Forellenweg 16
4941 SJ Raamsdonksveer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

One ml contains:

Active substance:
Meloxicam 20 mg

Excipient:
Ethanol 150 mg

4. INDICATIONS

Cattle:
For use in acute respiratory infection with appropriate antibiotic therapy to reduce clinical signs in cattle.
For use in diarrhoea in combination with oral rehydration therapy to reduce clinical signs in calves of over one week of age and young, non-lactating cattle.
For adjunctive therapy in the treatment of acute mastitis, in combination with antibiotic therapy.
For the relief of post-operative pain following dehorning in calves.

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

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

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

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

For the treatment of diarrhoea in cattle, do not use in animals of less than one week of age.

6. ADVERSE REACTIONS

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

In horses, a transient swelling at the injection site can occur but resolves without intervention.

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

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

7. TARGET SPECIES

Cattle, pigs and horses

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

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

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

Horses:
Single intravenous injection at a dosage of 0.6 mg meloxicam/kg body weight (i.e. 3.0 ml/100 kg body weight).

Avoid introduction of contaminated during use. The stopper should not be punctured more than 20 times.

9. ADVICE ON CORRECT ADMINISTRATION

In case of overdose symptomatic treatment should be initiated.
10. WITHDRAWAL PERIOD

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

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use after the expiry date stated on the label after EXP.
Shelf-life after first opening the container: 4 weeks.

12. SPECIAL WARNING(S)

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

Precautions to be taken by the person administering the product
Accidental self-injection may give rise to pain. People with known hypersensitivity to Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) should avoid contact with the veterinary medicinal product.
In case of accidental self-injection, seek medical advice immediately and show this package leaflet or the label to the physician.

Meloxicam may be harmful for the foetus and unborn child. Pregnant women and women of child-bearing potential should not administer this product.

Use during pregnancy and lactation
Cattle and pigs: Can be used during pregnancy and lactation.
Horses: Do not use in pregnant or lactating mares.

Interactions
Do not administer concurrently with glucocorticosteroids, other non-steroidal anti-inflammatory drugs or with anticoagulant agents.

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

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

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

15. OTHER INFORMATION

Package (size)
Colourless type I glass vials of 50 ml or 100 ml, closed with a rubber stopper and sealed with an aluminium cap.

Not all pack sizes may be marketed.
1. **NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder:
Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

Manufacturer for the batch release:
Produlab Pharma B.V.
Forellenweg 16
4941 SJ Raamsdonksveer
The Netherlands

2. **NAME OF THE VETERINARY MEDICINAL PRODUCT**

Meloxidolor 40 mg/ml solution for injection for cattle and horses

3. **STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS**

One ml contains:

**Active substance:**
Meloxicam 40 mg

**Excipient:**
Ethanol 150 mg

4. **INDICATIONS**

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

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

5. **CONTRAINDICATIONS**

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

For the treatment of diarrhoea in cattle, do not use in animals of less than one week of age.

6. ADVERSE REACTIONS

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

In horses, a transient swelling at the injection site can occur but resolves without intervention.

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

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

7. TARGET SPECIES

Cattle and horses

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

Cattle:
Single intravenous injection at a dosage of 0.5 mg meloxicam/kg body weight (i.e. 1.25 ml/100 kg body weight) in combination with antibiotic therapy or with oral re-hydration therapy, as appropriate.

Horses:
Single intravenous injection at a dosage of 0.6 mg meloxicam/kg body weight (i.e. 1.5 ml/100 kg body weight).

Avoid introduction of contamination during use. The stopper should not be punctured more than 20 times.

9. ADVICE ON CORRECT ADMINISTRATION

In case of overdose symptomatic treatment should be initiated.

10. WITHDRAWAL PERIOD

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

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use after the expiry date stated on the label after EXP.
Shelf-life after first opening the container: 4 weeks.

12. **SPECIAL WARNING(S)**

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

**Precautions to be taken by the person administering the product**
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**Interactions**
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**Overdose**
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13. **SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

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15. **OTHER INFORMATION**

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