ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Meloxicam: 5 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Ethanol	150 mg
Poloxamer 188	
Sodium chloride	
Glycine	
Sodium hydroxide	
Glycofurol	
Meglumine	
Water for injections	

Clear yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (calves and young cattle) and pigs.

3.2 Indications for use for each 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 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.

3.3 Contraindications

Do not use in animals suffering from impaired hepatic, cardiac or renal function or haemorrhagic disorders, or where there is evidence of ulcerogenic gastrointestinal lesions.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
For the treatment of diarrhoea in cattle, do not use in animals of less than one week of age.
Do not use in pigs less than 2 days old.

3.4 Special warnings

Treatment of calves with the veterinary medicinal product 20 minutes before dehorning reduces post-operative pain. The veterinary medicinal product alone will not provide adequate pain relief during the dehorning procedure. To obtain adequate pain relief during surgery co-medication with an appropriate analgesic is needed.

Treatment of piglets with the veterinary medicinal product 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 the veterinary medicinal product should be administered 30 minutes before surgical intervention.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Avoid use in very severely dehydrated, hypovolaemic or hypotensive animals which require parenteral rehydration, as there may be a potential risk of renal toxicity.

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

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

3.6 Adverse events

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site swelling[1] Anaphylactoid reaction[2]

[1] Following subcutaneous injection: slight and transient.
[2] May be serious (including fatal) and should be treated symptomatically.

Pigs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactoid reaction[1]

[1] May be serious (including fatal) and should be treated symptomatically.

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

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

3.7 Use during pregnancy, lactation or lay

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

3.8 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.

3.9 Administration routes and dosage

Cattle:
Single subcutaneous 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. To ensure a correct dosage, body weight should be determined as accurately as possible.

Avoid introduction of contamination during use.

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

In case of overdose symptomatic treatment should be initiated.

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

Not applicable.

3.12 Withdrawal periods

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AC06

4.2 Pharmacodynamics

Meloxicam is a Non-Steroidal Anti-Inflammatory Drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, anti-exudative, analgesic and antipyretic properties. Meloxicam also has anti-endotoxic properties because it has been shown to inhibit production of thromboxane B_2 induced by *E. coli* endotoxin administration in calves and pigs.

4.3 Pharmacokinetics

Absorption
After a single subcutaneous dose of 0.5 mg meloxicam/kg, C_{max} values of 2.1 mcg/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 mcg/ml was reached within 1 hour in pigs.

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

Metabolism
Meloxicam is predominantly found in plasma. In cattle, meloxicam is also a major excretion product in milk and bile whereas urine contains only traces of the parent compound. In pigs, bile and urine contain only traces of the parent compound. Meloxicam is metabolised to an alcohol, an acid derivative and to several polar metabolites. All major metabolites have been shown to be pharmacologically inactive.

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

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after first opening the immediate packaging: 28 days

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Cardboard box with 1 or 12 colourless glass injection vial(s) of 20 ml, 50 ml or 100 ml, closed with a rubber stopper and sealed with an aluminium cap.
Not all pack sizes may be marketed.

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

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

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

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/04/042/007: 1 x 20 ml
EU/2/04/042/009: 1 x 50 ml
EU/2/04/042/001: 1 x 100 ml
EU/2/04/042/008: 12 x 20 ml
EU/2/04/042/010: 12 x 50 ml
EU/2/04/042/002: 12 x 100 ml

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 02/03/2004

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

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Novem 20 mg/ml solution for injection for cattle and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Meloxicam: 20 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Ethanol	150 mg
Poloxamer 188	
Macrogol 300	
Glycine	
Disodium edetate	
Sodium hydroxide	
Hydrochloric acid	
Meglumine	
Water for injections	

Clear yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle and pigs

3.2 Indications for use for each 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 septicaemia and toxaemia (mastitis-metritis-agalactia syndrome) with appropriate antibiotic therapy.

3.3 Contraindications

Do not use in animals suffering from impaired hepatic, cardiac or renal function or 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.

3.4 Special warnings

Treatment of calves with the veterinary medicinal product 20 minutes before dehorning reduces post-operative pain. The veterinary medicinal product alone will not provide adequate pain relief during the dehorning procedure. To obtain adequate pain relief during surgery co-medication with an appropriate analgesic is needed.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Avoid use in very severely dehydrated, hypovolaemic or hypotensive animals which require parenteral rehydration, as there may be a potential risk of renal toxicity.

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

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

3.6 Adverse events

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site swelling[1] Anaphylactoid reaction[2]

[1] Following subcutaneous injection: slight and transient.
[2] May be serious (including fatal) and should be treated symptomatically.

Pigs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactoid reaction[1]

[1] May be serious (including fatal) and should be treated symptomatically.

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

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

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy and lactation.

3.8 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.

3.9 Administration routes and dosage

Cattle:
Single subcutaneous 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.

To ensure a correct dosage body weight should be determined as accurately as possible.

Avoid introduction of contamination during use.

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

In case of overdose, symptomatic treatment should be initiated.

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

Not applicable.

3.12 Withdrawal periods

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

4. PHARMACOLOGICAL PROPERTIES

4.1 ATCvet code: QM01AC06

4.2 Pharmacodynamics

Meloxicam is a Non-Steroidal Anti-Inflammatory Drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, 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 B_2 induced by *E. coli* endotoxin administration in calves, lactating cows and pigs.

4.3 Pharmacokinetics

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

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

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after first opening the immediate packaging: 28 days

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Cardboard box with either 1 or 12 colourless glass injection vials each containing 20 ml, 50 ml or 100 ml.
Cardboard box with either 1 or 6 colourless glass injection vial(s) each containing 250 ml.
Each vial is closed with a rubber stopper and sealed with an aluminium cap.

Not all pack sizes may be marketed.

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

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

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

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/04/042/005: 1 x 20 ml
EU/2/04/042/003: 1 x 50 ml
EU/2/04/042/004: 1 x 100 ml
EU/2/04/042/006: 1 x 250 ml
EU/2/04/042/011: 12 x 20 ml
EU/2/04/042/012: 12 x 50 ml
EU/2/04/042/013: 12 x 100 ml
EU/2/04/042/014: 6 x 250 ml

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 02/03/2004

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

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Novem 40 mg/ml solution for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Meloxicam: 40 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Ethanol	150 mg
Poloxamer 188	
Macrogol 300	
Glycine	
Disodium edetate	
Sodium hydroxide	
Hydrochloric acid	
Meglumine	
Water for injections	

Clear yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle

3.2 Indications for use for each target species

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.

3.3 Contraindications

Do not use in animals suffering from impaired hepatic, cardiac or renal function or 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 1 week of age.

3.4 Special warnings

Treatment of calves with the veterinary medicinal product20 minutes before dehorning reduces post-operative pain. The veterinary medicinal product alone will not provide adequate pain relief during the dehorning procedure. To obtain adequate pain relief during surgery co-medication with an appropriate analgesic is needed.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Avoid use in very severely dehydrated, hypovolaemic or hypotensive animals which require parenteral rehydration, as there may be a potential risk of renal toxicity.

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

In view of the risk of accidental self-injection and the known adverse class-effects of NSAIDs and other prostaglandin inhibitors on pregnancy and/or embryofoetal development, the veterinary medicinal product should not be administered by pregnant women or women attempting to conceive.
This veterinary medicinal product can cause eye irritation. In case of contact with the eyes, immediately rinse thoroughly with water.

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

3.6 Adverse events

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site swelling[1] Anaphylactoid reaction[2]

[1] Following subcutaneous injection: slight and transient.
[2] May be serious (including fatal) and should be treated symptomatically.

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

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

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Do not administer concurrently with glucocorticosteroids, other NSAIDs or with anticoagulant agents.

3.9 Administration routes and dosage

Single subcutaneous injection at a dose 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.

To ensure a correct dosage, body weight should be determined as accurately as possible.

Avoid introduction of contamination during use.

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

In case of overdose symptomatic treatment should be initiated.

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

Not applicable.

3.12 Withdrawal periods

Meat and offal: 15 days; milk: 5 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AC06

4.2 Pharmacodynamics

Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, 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 B_2 induced by *E. coli* endotoxin administration in calves and lactating cows.

4.3 Pharmacokinetics

Absorption
After a single subcutaneous dose of 0.5 mg meloxicam/kg, C_{max}values of 2.1 mcg/ml and 2.7 mcg/ml were reached after 7.7 hours and 4 hours in young cattle and lactating cows, respectively.

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.

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.

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

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Pack sizes of 1 or 12 colourless glass injection vial(s) each containing 50 ml or 100 ml.
Each vial is closed with a rubber stopper and sealed with an aluminium cap.
Not all pack sizes may be marketed.

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

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

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

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/04/042/015: 1 x 50 ml
EU/2/04/042/016: 1 x 100 ml
EU/2/04/042/017: 12 x 50 ml
EU/2/04/042/018: 12 x 100 ml

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 02/03/2004

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

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton for 20 ml, 50 ml and 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam: 5 mg/ml

3. PACKAGE SIZE

1 x 20 ml
1 x 50 ml
1 x 100 ml
12 x 20 ml
12 x 50 ml
12 x 100 ml

4. TARGET SPECIES

Cattle (calves and young cattle) and pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cattle: s.c. injection.
Pigs: i.m. injection. If required, a second administration can be given after 24 hours.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle: meat and offal: 15 days
Pigs: meat and offal: 5 days

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

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

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

14. MARKETING AUTHORISATION NUMBERS

EU/2/04/042/007 1 x 20 ml
EU/2/04/042/009 1 x 50 ml
EU/2/04/042/001 1 x 100 ml
EU/2/04/042/008 12 x 20 ml
EU/2/04/042/010 12 x 50 ml
EU/2/04/042/002 12 x 100 ml

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vial, 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam: 5 mg/ml

100 ml

3. TARGET SPECIES

Cattle (calves and young cattle) and pigs

4. ROUTES OF ADMINISTRATION

Cattle: s.c.injection.
Pigs: i.m. injection.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period(s):
Cattle: meat and offal: 15 days
Pigs: meat and offal: 5 days

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 28 days.

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vials, 20 ml and 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Novem 5 mg/ml for cattle and pigs

2. QUANITITTATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Meloxicam: 5 mg/ml

20 ml
50 ml

Cattle: s.c.
Pigs: i.m.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 28 days.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Novem 20 mg/ml solution for injection for cattle and pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam: 20 mg/ml

3. PACKAGE SIZE

1 x 20 ml
1 x 50 ml
1 x 100 ml
1 x 250 ml
12 x 20 ml
12 x 50 ml
12 x 100 ml
6 x 250 ml

4. TARGET SPECIES

Cattle and pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cattle: s.c.injection.
Pigs: i.m.injection. If required, a second administration can be given after 24 hours.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle: meat and offal: 15 days; milk: 5 days
Pigs: meat and offal: 5 days

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

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

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

14. MARKETING AUTHORISATION NUMBERS

EU/2/04/042/005 1 x 20 ml
EU/2/04/042/003 1 x 50 ml
EU/2/04/042/004 1 x 100 ml
EU/2/04/042/006 1 x 250 ml
EU/2/04/042/011 12 x 20 ml
EU/2/04/042/012 12 x 50 ml
EU/2/04/042/013 12 x 100 ml
EU/2/04/042/014 6 x 250 ml

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vials, 100 ml and 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Novem 20 mg/ml solution for injection for cattle and pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam: 20 mg/ml

100 ml
250 ml

3. TARGET SPECIES

Cattle and pigs

4. ROUTES OF ADMINISTRATION

Cattle: s.c.injection.
Pigs: i.m.injection.

5. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle: meat and offal: 15 days; milk: 5 days
Pigs: meat and offal: 5 days

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 28 days.

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vials, 20 ml and 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Novem 20 mg/ml for cattle and pigs

2. QUANITITTATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Meloxicam: 20 mg/ml

20 ml
50 ml

Cattle: s.c.
Pigs: i.m.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 28 days.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton for 50 ml and 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Novem 40 mg/ml solution for injection for cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam: 40 mg/ml

3. PACKAGE SIZE

50 ml
100 ml
12 x 50 ml
12 x 100 ml

4. TARGET SPECIES

Cattle

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

s.c. injection.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 15 days; milk: 5 days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

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

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

14. MARKETING AUTHORISATION NUMBER(S)

EU/2/04/042/015 50 ml
EU/2/04/042/016 100 ml
EU/2/04/042/017 12 x 50 ml
EU/2/04/042/018 12 x 100 ml

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vial, 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Novem 40 mg/ml solution for injection for cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam: 40 mg/ml

100 ml

3. TARGET SPECIES

Cattle

4. ROUTES OF ADMINISTRATION

s.c. injection.

5. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 15 days; milk: 5 days.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 28 days.

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL, 50 ML

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Novem 40 mg/ml for cattle

2. QUANITITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Meloxicam: 40 mg/ml

50 ml

s.c.

4. BATCH NUMBER

Lot {number}

5. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 28 days.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each ml contains:
Active substance: Meloxicam: 5 mg
Excipient: Ethanol: 150 mg

Clear yellow solution.

3. Target species

Cattle (calves and young cattle) and pigs

4. Indications for use

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

6. Special warnings

Treatment of calves with the veterinary medicinal product 20 minutes before dehorning reduces post-operative pain. The veterinary medicinal product alone will not provide adequate pain relief during the dehorning procedure. To obtain adequate pain relief during surgery co-medication with an appropriate analgesic is needed.

Treatment of piglets with the veterinary medicinal product 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 the veterinary medicinal product should be administered 30 minutes before surgical intervention.

Special precautions for safe use in the target species:
If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.
Avoid use in very severely dehydrated, hypovolaemic or hypotensive animals which require parenteral rehydration, as there may be a potential risk of renal toxicity.

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

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

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

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

Major incompatibilities:
None known.

7. Adverse events

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
- Injection site swelling[1].
- Anaphylactoid reaction[2]

[1] Following subcutaneous injection: slight and transient.
[2] May be serious (including fatal) and should be treated symptomatically.

Pigs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Anaphylactoid reaction[1]

[1] May be serious (including fatal) and should be treated symptomatically.

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

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

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

Cattle:
Single subcutaneous 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. To ensure a correct dosage, body weight should be determined as accurately as possible.
Avoid introduction of contamination during use.

10. Withdrawal periods

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: 28 days.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and vial after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

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

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/04/042/007-010, EU/2/04/042/001-002

Cardboard box with 1 or 12 colourless glass injection vial(s) of either 20 ml, 50 ml or 100 ml.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

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

16. Contact details

Marketing authorisation holder:
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Germany

Manufacturer responsible for batch release:
Labiana Life Sciences S.A.
Venus, 26
Can Parellada Industrial
08228 Terrassa
Spain

Local representatives and contact details to report suspected adverse reactions:

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United Kingdom (Northern Ireland)
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PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Novem 20 mg/ml solution for injection for cattle and pigs

2. Composition

Each ml contains:
Active substance: Meloxicam: 20 mg
Excipient: Ethanol: 150 mg

Clear yellow solution.

3. Target species

Cattle and pigs

4. Indications for use

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 septicaemia and toxaemia (mastitis-metritis-agalactia syndrome) with appropriate antibiotic therapy.

5. Contraindications

Do not use in animals suffering from impaired hepatic, cardiac or renal function or 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. Special warnings

Treatment of calves with the veterinary medicinal product 20 minutes before dehorning reduces post-operative pain. The veterinary medicinal product alone will not provide adequate pain relief during the dehorning procedure. To obtain adequate pain relief during surgery co-medication with an appropriate analgesic is needed.

Special precautions for safe use in the target species:
If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

Avoid use in very severely dehydrated, hypovolaemic or hypotensive animals which require parenteral rehydration, as there may be a potential risk of renal toxicity.

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

Pregnancy and lactation:
Can be used during pregnancy and lactation.

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

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

Major incompatibilities:
None known.

7. Adverse events

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
- Injection site swelling[1].
- Anaphylactoid reaction[2]

[1] Following subcutaneous injection: slight and transient.
[2] May be serious (including fatal) and should be treated symptomatically.

Pigs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Anaphylactoid reaction[1].

[1] May be serious (including fatal) and should be treated symptomatically.

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

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

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

Cattle:

Single subcutaneous 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.

9. Advice on correct administration

To ensure a correct dosage body weight should be determined as accurately as possible.
Avoid introduction of contamination during use.

10. Withdrawal periods

Cattle: meat and offal: 15 days; milk: 5 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: 28 days.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and vial after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

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

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/04/042/003-006, , EU/2/04/042/011-014

Cardboard box with 1 or 12 colourless glass injection vial(s) of either 20 ml, 50 ml or 100 ml.
Cardboard box with 1 or 6 colourless glass injection vial(s) of 250 ml.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

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

16. Contact details

Marketing authorisation holder:
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Germany

Manufacturer responsible for batch release:
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Local representatives and contact details to report suspected adverse reactions:

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PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Novem 40 mg/ml solution for injection for cattle

2. Composition

Each ml contains:
Active substance: Meloxicam: 40 mg
Excipient: Ethanol: 150 mg

Clear yellow solution.

3. Target species

Cattle

4. Indications for use

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.

5. Contraindications

Do not use in animals suffering from impaired hepatic, cardiac or renal function or 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 1 week of age.

6. Special warnings

Treatment of calves with the veterinary medicinal product 20 minutes before dehorning reduces post-operative pain. The veterinary medicinal product alone will not provide adequate pain relief during the dehorning procedure. To obtain adequate pain relief during surgery co-medication with an appropriate analgesic is needed.

Special precautions for safe use in the target species:
If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.
Avoid use in very severely dehydrated, hypovolaemic or hypotensive animals which require parenteral rehydration, as there may be a potential risk of renal toxicity.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Accidental self-injection may give rise to pain. People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the veterinary medicinal product.

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

In view of the risk of accidental self-injection and the known adverse class-effects of NSAIDs and other prostaglandin inhibitors on pregnancy and/or embryofoetal development, the veterinary medicinal product should not be administered by pregnant women or women attempting to conceive. This veterinary medicinal product can cause eye irritation. In case of contact with the eyes, immediately rinse thoroughly with water.

Pregnancy and lactation:
Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
Do not administer concurrently with glucocorticosteroids, other NSAIDs or with anticoagulant agents.

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

Major incompatibilities:
None known.

7. Adverse events

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
- Injection site swelling[1]
- Anaphylactoid reaction[2]

[1] Following subcutaneous injection: slight and transient.
[2] May be serious (including fatal) and should be treated symptomatically.

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

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder, the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:{national system details}

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

Single subcutaneous injection at a dose 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.

9. Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible.
Avoid introduction of contamination during use.

10. Withdrawal periods

Meat and offal: 15 days; milk: 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: 28 days.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and vial after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

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

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/04/042/015-018

Pack sizes of 1 or 12 colourless glass injection vial(s) of either 50 ml or 100 ml.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

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

16. Contact details

Marketing authorisation holder:
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Germany

Manufacturer responsible for batch release:
Labiana Life Sciences S.A.
Venus, 26
Can Parellada Industrial
08228 Terrassa
Spain

Local representatives and contact details to report suspected adverse reactions:

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