ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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
Anhydrous citric acid	
Poloxamer 188	
Meglumine	
Glycine	
Macrogol 300	
Sodium hydroxide (for pH adjustment)	
Hydrochloric acid (for pH adjustment)	
Water for injections	

Clear yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, pigs and horses.

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.

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.

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.

3.3 Contraindications

See also section 3.7.

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 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.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
If verse 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.

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):	Anaphylactoid reaction[1], Injection site swelling[2]

[1]May be serious (including fatal) and should be treated symptomatically.
[2]Slight and transient following subcutaneous administration.

Pigs:

Very rare	Anaphylactoid reaction[1]

(<1 animal / 10 000 animals treated, including isolated reports):	

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

Horses:

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

[1]May be serious (including fatal) and should be treated symptomatically.
[2]Transient. Resolves without intervention.

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

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 anti-coagulant agents.

3.9 Administration routes and dosage

Cattle:
Single subcutaneous or intravenous injection at a dose 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 dose of 0.4 mg meloxicam/kg body weight (i.e. 2 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 dose of 0.6 mg meloxicam/kg body weight (i.e. 3 ml/100 kg body weight).
For use in the alleviation of inflammation and the relief of pain in both acute and chronic musculo–skeletal disorders, oral suspensions of meloxicam may be used for continuation of treatment at a dosage of 0.6 mg meloxicam/kg body weight, 24 hours after administration of the injection.

Avoid introduction of contamination during use.
Do not broach the stopper more than 50 times.

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

In the 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.

Horses:
Meat and offal: 5 days.
Not authorised for use in horses producing milk for human consumption.

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 B2 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 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_{max} 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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

Type I clear glass vial with Teflon coated bromobutyl rubber stoppers and sealed with an aluminium flip-off tear-off seal.

Cardboard box with 1 x 10 ml vial.
Cardboard box with 1 x 50 ml vial.
Cardboard box with 1 x 100 ml vial.
Cardboard box with 1 x 250 ml vial.

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

Bimeda Animal Health Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/11/133/001-004

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 13/09/2011

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

DD/MM/YYYY

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard Box: 10 ml, 50 ml, 100 ml or 250 ml vials.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 20 mg/ml

3. PACKAGE SIZE

1 x 10 ml
1 x 50 ml
1 x 100 ml
1 x 250 ml

4. TARGET SPECIES

Cattle, pigs and horses.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cattle: ***s.c. i.v.***

Pigs: ***i.m.***

Horses: ***i.v.***

Do not broach the stopper more than 50 times.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle: Meat and offal: 15 days.
Milk: 5 days.

Pigs: Meat and offal: 5 days.

Horses: eat and offal: 5 days.
Not authorised for use in horses producing milk for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}

Shelf-life after first opening the container: 28 days
Once broached, use by…

9. SPECIAL STORAGE PRECAUTIONS

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

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Ltd.

14. MARKETING AUTHORISATION NUMBERS

EU/2/11/133/001 (10 ml)
EU/2/11/133/002 (50 ml)
EU/2/11/133/003 (100 ml)
EU/2/11/133/004 (250 ml)

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Glass vial label for 50 ml, 100 ml and 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 20 mg/ml

3. TARGET SPECIES

Cattle, pigs and horses

4. ROUTES OF ADMINISTRATION

Cattle: **s.c. i.v.**
Pigs: **i.m.**
Horses: **i.v.**

Read the package leaflet before use.
Do not broach more than 50 times.

5. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle: Meat and offal: 15 days.
Milk: 5 days.

Pigs: Meat and offal: 5 days.

Horses: Meat and offal: 5 days.
Not authorised for use in horses producing milk for human consumption.

6. EXPIRY DATE

Exp. {mm/yyyy}

Shelf-life after first opening the container: 28 days
Once broached, use by ….

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass vial label for 10 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Meloxicam 20 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Shelf-life after first opening the container: 28 days
Once broached, use by ….

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each ml contains:

Active substance:
Meloxicam 20 mg

Excipients:
Ethanol 150 mg

Clear yellow solution.

3. Target species

Cattle, pigs and horses.

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.

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.

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 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 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.

6. Special warnings

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.
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.

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

Horses:
Do not use in pregnant or lactating mares.

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

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

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Cattle:

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

[1]May be serious (including fatal) and should be treated symptomatically.
[2]Slight and transient following subcutaneous administration.

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.

Horses:

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

[1]May be serious (including fatal) and should be treated symptomatically.
[2]Transient. Resolves without intervention.

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 (***s.c.***) or intravenous (***i.v.***) injection at a dose 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 (***i.m.***) injection at a dose of 0.4 mg meloxicam/kg body weight (i.e. 2 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 (***i.v.***) injection at a dose of 0.6 mg meloxicam/kg body weight (i.e. 3 ml/100 kg body weight).
For use in the alleviation of inflammation and the relief of pain in both acute and chronic musculo–skeletal disorders, oral suspensions of meloxicam may be used for continuation of treatment at a dosage of 0.6 mg meloxicam/kg body weight, 24 hours after administration of the injection.

9. Advice on correct administration

Avoid introduction of contamination during use.
Do not broach the stopper more than 50 times.

10. Withdrawal periods

Cattle:
Meat and offal: 15 days.
Milk: 5 days.

Pigs:
Meat and offal: 5 days.

Horses:
Meat and offal: 5 days.
Not authorised for use in horses producing milk for human consumption.

11. Special storage precautions

Keep out of the sight and reach of children.

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

Shelf life after first opening the immediate packaging: 28 days.

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

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

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/2/11/133/001 (10 ml)
EU/2/11/133/002 (50 ml)
EU/2/11/133/003 (100 ml)
EU/2/11/133/004 (250 ml)

Type I clear glass vial with Teflon coated bromobutyl rubber stoppers and sealed with an aluminium flip-off tear-off seal.

Cardboard box with 1 x 10 ml vial.
Cardboard box with 1 x 50 ml vial.
Cardboard box with 1 x 100 ml vial.
Cardboard box with 1 x 250 ml vial.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

DD/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:
Bimeda Animal Health Limited,

2, 3 & 4 Airton Close,
Tallaght, Dublin 24,
Ireland.

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

Local representatives and contact details to report suspected adverse events:

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E-mail: info.vet@kela.health

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