ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Novaquin 15 mg/ml oral suspension for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Meloxicam 15 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Sodium benzoate	1.75 mg
Glycerol	
Polysorbate 80	
Hydroxyethylcellulose	
Silica, colloidal anhydrous	
Disodium phosphate dodecahydrate	
Citric acid monohydrate	
Sodium cyclamate	
Sorbitol, liquid	
Sucralose	
Anise aroma	
Water, purified	

Yellowish-green viscous suspension.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

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

3.3 Contraindications

Do not use in horses suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in horses less than 6 weeks of age.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Avoid use in any dehydrated, hypovolemic or hypotensive animals as there is a potential risk of renal toxicity.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) should avoid contact with the veterinary medicinal product.

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

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

Horses:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Diarrhoea[a], Abdominal pain, Colitis Appetite loss, Lethargy Urticaria[a], Anaphylactoid reaction[b]

[a] Reversible.
[b] 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 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:
Laboratory studies in cattle have not provided any evidence for teratogenic, foetotoxic, or maternotoxic effects. However, no data have been generated in horses. Therefore do not use the veterinary medicinal product in pregnant or lactating mares.

3.8 Interaction with other medicinal products and other forms of interaction

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

3.9 Administration routes and dosage

For oral use.

To be administered either mixed with food or directly into the mouth at a dosage of 0.6 mg/kg body weight, once daily, up to 14 days. In case the product is mixed with food, it should be added to a small quantity of food, prior to feeding.

The suspension should be given using the measuring syringe provided in the package. The syringe fits onto the bottle and has a kg-body weight scale.

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

Shake vigorously at least 20 times before use.

After administration of the veterinary medicinal product, close the bottle by replacing the cap, wash the measuring syringe with warm water and let it dry.

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

Meat and offal: 3 days.

Not authorised for use in mares 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, analgesic, anti-exudative and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it also inhibits collagen-induced thrombocyte aggregation. Meloxicam also has anti-endotoxic properties because it has been shown to inhibit production of thromboxane B_2 induced by intravenous *E. coli* endotoxin administration in calves and pigs.

4.3 Pharmacokinetics

Absorption
When the product is used according to the recommended dosage regime the oral bioavailability is approximately 98 %. Maximal plasma concentrations are obtained after approximately 2 – 3 hours. The accumulation factor of 1.08 suggests that meloxicam does not accumulate when administered daily.

Distribution
Approximately 98 % of meloxicam is bound to plasma proteins. The volume of distribution is 0.12 l/kg.

Metabolism
The metabolism is qualitatively similar in rats, mini-pigs, humans, cattle and pigs although quantitatively there are differences. The major metabolites found in all species were the 5-hydroxy- and 5-carboxy-metabolites and the oxalyl-metabolite. The metabolism in horses was not investigated. All major metabolites have been shown to be pharmacologically inactive.

Elimination
Meloxicam is eliminated with a terminal half-life of 7.7 hours.

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: 5 months.

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 one high density polyethylene (HDPE) bottle of 125 ml or 336 ml with a HDPE screw cap and a polypropylene measuring syringe.

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

Le Vet Beheer B.V.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/15/186/001-002

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 08/09/2015.

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

Outer carton/Bottle 125 ml or 336 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Novaquin 15 mg/ml oral suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:
Meloxicam 15 mg

3. PACKAGE SIZE

125 ml
336 ml

4. TARGET SPECIES

Horses

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.
Shake vigorously at least 20 times before use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 3 days.
Not authorised for use in mares producing milk for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within: 5 months.

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

Le Vet Beheer B.V.

14. MARKETING AUTHORISATION NUMBERS

EU/2/15/186/001 125 ml
EU/2/15/186/002 336 ml

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL/HDPE Bottle 125 ml or 336 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Novaquin 15 mg/ml oral suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:
Meloxicam 15 mg

3. TARGET SPECIES

Horses

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.
Oral use.
Shake vigorously at least 20 times before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 3 days.
Not authorised for use in mares producing milk for human consumption.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within: 5 months.

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Le Vet Beheer B.V.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Novaquin 15 mg/ml oral suspension for horses

2. Composition

Each ml contains:

Active substance
Meloxicam 15 mg

Excipients
Sodium benzoate 1.75 mg

Yellowish-green viscous suspension.

3. Target species

Horses.

4. Indications for use

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

5. Contraindications

Do not use in horses suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in horses less than 6 weeks of age.

6. Special warnings

Special precautions for safe use in the target species:
Avoid use in any dehydrated, hypovolemic or hypotensive animal, as there is a potential risk of renal toxicity.

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

Pregnancy and lactation:
Laboratory studies in cattle have not provided any evidence for teratogenic, foetotoxic, or maternotoxic effects. However, no data have been generated in horses
Do not use the veterinary medicinal product in pregnant or lactating mares.

Interaction with other medicinal products and other forms of interaction:
Do not administer concurrently with glucocorticoids, 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

Horses:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Diarrhoea[a], Abdominal pain, Colitis Appetite loss, Lethargy Urticaria (hives)[a], Anaphylactoid reaction[b]

[a] Reversible.
[b] 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 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

For oral use.

Dosage
Oral suspension to be administered at a dosage of 0.6 mg/kg body weight, once daily, up to 14 days.

Method and route of administration
Shake vigorously at least 20 times before use. The suspension should be given using the measuring syringe provided in the package. The syringe fits onto the bottle and has a kg-body weight scale.
To be administered either mixed with a small quantity of food, prior to feeding, or directly into the mouth.

9. Advice on correct administration

Avoid introduction of contamination during use.

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

After administration of the veterinary medicinal product, close the bottle by replacing the cap, wash the measuring syringe with warm water and let it dry.

10. Withdrawal periods

Meat and offal: 3 days.
Not authorised for use in mares 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 this veterinary medicinal product after the expiry date which is stated on the carton and the bottle after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 5 months.

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.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/15/186/001-002

Cardboard box with one bottle of either 125 ml or 336 ml with a screw cap and a measuring syringe.

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 and contact details to report suspected adverse events:
Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands
Tel: +31 348 563 434

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