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

One ml contains:

Active substance:
Meloxicam 15 mg

Excipients:
Sodium benzoate 1.75 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension.
Yellowish-green viscous oral suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Horses.

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

Do not use in pregnant or lactating mares.
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.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
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.

4.6 Adverse reactions (frequency and seriousness)

Isolated cases of adverse reactions typically associated with NSAIDs were observed in clinical trials (slight urticaria, diarrhoea). The clinical signs were reversible.

Loss of appetite, lethargy, abdominal pain and colitis have been reported in very rare cases.

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

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

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

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 product during pregnancy and lactation (see section 4.3).

4.8 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.

4.9 Amounts to be administered and administration route

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.

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.

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

In case of overdose symptomatic treatment should be initiated.

4.11 Withdrawal period(s)

Meat and offal: 3 days.
Not authorised for use in mares 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, 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 B2 induced by intravenous *E. coli* endotoxin administration in calves and pigs.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium benzoate
Glycerol
Polysorbate 80
Hydroxyethylcellulose
Silica, colloidal anhydrous

Disodium phosphate dodecahydrate
Citric acid monohydrate
Sodium cyclamate
Sorbitol, liquid
Sucralose
Anise aroma
Water, purified

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf-life after first opening of the immediate packaging: 5 months.

6.4. Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Cardboard box containing 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.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product 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

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/15/186/001-002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 08/09/2015
Date of last renewal:

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 REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

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

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Meloxicam	Meloxicam	Bovine, caprine, porcine, rabbit, *Equidae*	20 µg/kg 65 µg/kg 65 µg/kg	Muscle Liver Kidney	No entry	Anti-inflammatory agents/Non-steroidal anti-inflammatory agents
		Bovine, caprine	15 µg/kg	Milk		

The excipients listed in section 6.1 of the SPC are either allowed substances for which table 1 of 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

Outer carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Novaquin 15 mg/ml oral suspension for horses
meloxicam

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 15 mg/ml

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

125 ml
336 ml

5. TARGET SPECIES

Horses

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Meat and offal: 3 days.
Not authorised for use in mares producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

The suspension should be given using the measuring syringe provided in the package.

10. EXPIRY DATE

EXP {month/year}
Once opened use within: 5 months.

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet before use.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.

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

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

HDPE-bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Novaquin 15 mg/ml oral suspension for horses
meloxicam

2. STATEMENT OF THE ACTIVE SUBSTANCE(S)

Meloxicam 15 mg/ml

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

125 ml
336 ml

5. TARGET SPECIES

Horses

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Meat and offal: 3 days.
Not authorised for use in mares producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP (month/year)
Once opened use within: 5 months.
.

11. SPECIAL STORAGE CONDITIONS

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.
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

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

17. MANUFACTURER'S BATCH NUMBER

Batch

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Novaquin 15 mg/ml oral suspension for 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 responsible for batch release:
Produlab Pharma B.V.
Forellenweg 16
4941 SJ Raamsdonksveer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Novaquin 15 mg/ml oral suspension for horses
Meloxicam

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

One ml contains:

Active substance
Meloxicam 15 mg.

Excipients
Sodium benzoate 1.75 mg

Yellowish-green viscous oral suspension.

4. INDICATION(S)

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

5. CONTRAINDICATIONS

Do not use in pregnant or lactating mares.
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. ADVERSE REACTIONS

Isolated cases of adverse reactions typically associated with Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) were observed in clinical trials (slight urticaria, diarrhoea). The clinical signs were reversible.
Loss of appetite, lethargy, abdominal pain and colitis have been reported in very rare cases.
Anaphylactoid reactions, which may be serious (including fatal), may occur in very rare cases and should be treated symptomatically.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals, including isolated reports treated).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Horses.

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

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. 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.

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.

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 PERIOD(S)

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.

Shelf-life after first opening of the container: 5 months.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
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 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.

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 in pregnant or lactating mares. See section "Contraindications".

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 (symptoms, emergency procedures, antidotes):
In case of overdose symptomatic treatment should be initiated.

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

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

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

Cardboard box containing one bottle of 125 ml
Cardboard box containing one bottle of 336 ml.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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