ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Quadrisol 100 mg/ml oral gel for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Vedaprofen 100 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Water (minimum purified grade)	
Propylene glycol (E1520)	130 mg
Hydroxyethylcellulose	
Potassium hydroxide (E525)	
Hydrochloric acid (E507)	
Chocolate flavour	

Clear colourless gel.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

Reduction of inflammation and relief of pain associated with musculo-skeletal disorders and soft tissue lesions (traumatic injuries and surgical trauma). In cases of anticipated surgical trauma, this veterinary medicinal product can be given prophylactically at least 3 hours prior to elective surgery.

3.3 Contraindications

Do not use in animals suffering from alimentary tract disorders, impaired heart, liver and kidney function.
Do not use in foals under the age of 6 months.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

Horses intended for racing and competition should be treated according to local requirements. Appropriate precautions must be taken for such horses to ensure compliance with competition regulations. In case of doubt, it is advisable to test the urine.

3.5 Special precautions for use

Special precautions for safe use in the target species:

If side effects occur, treatment should be discontinued. Horses with oral lesions should be assessed clinically and the attending veterinarian should take a decision as to whether treatment should be continued. If oral lesions persist, treatment should be discontinued.

Horses should be monitored for oral lesions during treatment. Avoid use in any dehydrated, hypovolaemic or hypotensive animals, as there may be potential risk of increased renal toxicity

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

In case of accidental ingestion, 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

Horses:

Undetermined frequency (cannot be estimated from the available data):	Digestive tract disorder[1] Soft stool[2] Urticaria[2] Lethargy[2]

[1] Lesions in the alimentary tract.
[2] Reversible.

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

Lactation:
The safety of the veterinary medicinal product has not been established during lactation.
Do not use in lactating mares.

Pregnancy:
Can be used during pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

Other NSAIDs, diuretics and substances with high protein binding may compete for binding and lead to toxic effects. This veterinary medicinal product must not be given with other NSAIDs or glucocorticosteroids.

3.9 Administration routes and dosage

Oral use.

Twice daily administration. An initial dose of 2 mg/kg (2 ml/100 kg) is followed by a maintenance dose of 1 mg/kg (1 ml/100 kg) given every 12 hours. Treatment can be continued for a maximum of 14 consecutive days. In case of prophylactic treatment, a maximum duration of treatment of 7 consecutive days is sufficient.

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

The gel is administered orally by inserting the nozzle of the syringe through the interdental space and depositing the required amount of gel on the back of the tongue. Before administration, the syringe should be adjusted to the calculated dosage by setting the ring on the plunger.

It is advisable to administer the product before feeding.

In cases of anticipated surgical trauma, the veterinary medicinal product can be given prophylactically at least 3 hours prior to elective surgery.

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

Lesions and bleedings in the alimentary tract, diarrhoea, urticaria, lethargy, inappetence. If symptoms occur, treatment should be discontinued. Symptoms are reversible. Overdosing may lead to death of treated animals.

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: 12 days.
Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AE90

4.2 Pharmacodynamics

Vedaprofen is a non-steroidal anti-inflammatory drug (NSAID) belonging to the propionic acid derivate group. Vedaprofen inhibits the prostaglandin synthesis enzyme system (cyclo-oxygenase enzyme) and thus possesses anti-inflammatory, antipyretic and analgesic properties. Studies in the horse have demonstrated potent inhibition of prostaglandin E_2 (PG E_2) synthesis in exudate and thromboxane B_2 synthesis in serum and exudate. Vedaprofen contains an asymmetric carbon atom and, therefore, is a racemic mixture of a (+) enantiomer and a (-) enantiomer. Both enantiomers contribute to therapeutic actions of the compound. The (+) enantiomer is more potent in inhibiting prostaglandin synthesis. Both enantiomers are equipotent $PGF_{2\alpha}$ antagonists.

4.3 Pharmacokinetics

Vedaprofen is rapidly absorbed following oral administration. Bioavailability after oral administration is 80-90 %, but is reduced significantly if medication is administered with food. The terminal half-life following oral administration is 350-500 minutes and no accumulation occurs following repeated oral dosing. Steady state is reached quickly following onset of treatment. Vedaprofen is highly bound to plasma proteins and extensively metabolised. The most abundant metabolite is a monohydroxylated derivative. All metabolites of vedaprofen were shown to be less

active than the parent compound as determined by a thromboxane B2 formation inhibition assay. Approximately 70 % of an orally administered dose is excreted in the urine.

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: 2 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

A 30 ml multidose syringe consisting of high density polyethylene (white) and low density polyethylene (white and natural). The syringe is fitted with variable dose capability, adjustable in steps of 0.5 ml and graduated to 1 ml.

Pack sizes:
Cardboard box with 1 syringe of 30 ml.
Cardboard box with 3 syringes of 30 ml.

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

GROVET B.V.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/97/005/001
EU/2/97/005/005

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 4 December 1997

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

{DD month 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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Quadrisol 100 mg/ml oral gel

2. STATEMENT OF ACTIVE SUBSTANCES

Vedaprofen 100 mg/ml

3. PACKAGE SIZE

1 x 30 ml
3 x 30 ml

4. TARGET SPECIES

Horses.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 12 days.
Not authorised for use in animals producing milk for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 2 months.
Once opened, 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

GROVET B.V

14. MARKETING AUTHORISATION NUMBERS

EU/2/97/005/001 (1 x 30 ml)
EU/2/97/005/005 (3 x 30 ml)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

30 ml syringe (HDP/LDP)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Quadrisol

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE

Vedaprofen 100 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 2 months.
Once broached, use by _____.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Quadrisol 100 mg/ml oral gel for horses

2. Composition

Each ml contains:

Active substance:
Vedaprofen 100 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Propylene glycol (E1520)	130 mg

Clear colourless gel.

3. Target species

Horses

4. Indications for use

Reduction of inflammation and relief of pain associated with musculo-skeletal disorders and soft tissue lesions (traumatic injuries and surgical trauma). In cases of anticipated surgical trauma, this veterinary medicinal product can be given prophylactically at least 3 hours prior to elective surgery.

5. Contraindications

Do not use in animals suffering from alimentary tract disorders, impaired heart, liver and kidney function.
Do not use in foals under the age of 6 months.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special warnings:
Horses intended for racing and competition should be treated according to local requirements. Appropriate precautions must be taken for such horses to ensure compliance with competition regulations. In case of doubt, it is advisable to test the urine.

Special precautions for safe use in the target species:
If side effects occur, treatment should be discontinued. Horses with oral lesions should be assessed clinically and the attending veterinarian should take a decision as to whether treatment should be continued. If oral lesions persist, treatment should be discontinued.

Horses should be monitored for oral lesions during treatment. Avoid use in any dehydrated, hypovolaemic or hypotensive animals, as there may be potential risk of increased renal toxicity

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during lactation.
Do not use in lactating mares.
The veterinary medicinal product can be used during pregnancy.

Interaction with other medicinal products and other forms of interaction:
Other NSAIDs, diuretics and substances with high protein binding may compete for binding and lead to toxic effects. This veterinary medicinal product must not be given with other NSAIDs or glucocorticosteroids.

Overdose:
Lesions and bleedings in the alimentary tract, diarrhoea, urticaria, lethargy, inappetence. If symptoms occur, treatment should be discontinued. Symptoms are reversible. Overdosing may lead to death of treated animals.

Major incompatibilities:
None.

7. Adverse events

Horses:

Undetermined frequency (cannot be estimated from the available data):	Digestive tract disorder[1] Soft stool[2] Urticaria[2] (hives) Lethargy[2]

[1] Lesions in the alimentary tract.
[2] Reversible.

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

Oral use.

The veterinary medicinal product is intended for twice daily administration. The dosage is an initial dose of 2 mg/kg (2 ml/100 kg) followed by a maintenance dose of 1 mg/kg (1 ml/100 kg) given every 12 hours.
Treatment can be continued for a maximum of 14 consecutive days. Bodyweight and dosage rate must be accurately determined to avoid overdosing. In case of prophylactic treatment, a maximum duration of treatment of 7 consecutive days is sufficient.

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

9. Advice on correct administration

The gel is administered orally by inserting the nozzle of the syringe through the interdental space and depositing the required amount of gel on the back of the tongue. Before administration, the syringe should be adjusted to the calculated dosage by setting the ring on the plunger.

It is advisable to administer the product before feeding.

10. Withdrawal periods

Meat and offal: 12 days.
Not authorised for use in animals 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 label and box after Exp. The expiry date refers to the last day of that month.

Shelf-life after first opening the immediate packaging: 2 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/2/97/005/001
EU/2/97/005/005

A 30 ml multidose syringe consisting of high density polyethylene (white) and low density polyethylene (white and natural). The syringe is fitted with variable dose capability, adjustable in steps of 0.5 ml and graduated to 1 ml.

Pack sizes:
Cardboard box with 1 syringe of 30 ml.

Cardboard box with 3 syringes of 30 ml.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD month 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 reactions:
GROVET B.V.
Centurionbaan 140
3769 AV Soesterberg
Netherlands
Tel: +31 88 582 4100

Manufacturer responsible for batch release:
Provet A.E.
Nikiforou Foka & Agion Anargyron,
Thesi Vrago, Aspropyrgos, 193 00,
Greece

Local representatives and contact details to report suspected adverse reactions:

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