ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Peptizole 370 mg/g Oral Paste for Horses (AU, CZ, ES, EE, FI, HU, IE, IT, LT, LV, PL, SK)
Ulcergold 370 mg/g Oral Paste for Horses (BE, LU, NL, PT, UK-NI)
Equinor 370 mg/g Oral Paste for Horses (FR)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance:
Omeprazole: 370 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Yellow Iron Oxide (E 172)	2 mg
Ethanolamine	
Cinnamon Leaf Oil	
Liquid Paraffin	

A yellow to tan oily paste.

3. CLINICAL INFORMATION

3.1. Target species

Horses.

3.2. Indications for use for each target species

For treatment and prevention of gastric ulcers in horses.

3.3. Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4. Special warnings

Not recommended for animals under 4 weeks of age or weighing less than 70 kg bodyweight.
The veterinarian should consider the need for performing relevant diagnostic tests before selection of the treatment dose rate.

3.5. Special precautions for use

Special precautions for safe use in the target species:

Stress (including high performance training and competition), feeding, management and husbandry practices may be associated with the development of gastric ulceration in horses. Individuals responsible for the wellbeing of horses should consider reducing the ulcerogenic challenge by modifying husbandry practices to achieve one or more of the following: reduced stress, reduced fasting, increased intake of roughage and access to grazing.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
As this veterinary medicinal product may cause irritant and hypersensitivity reactions, avoid direct contact with skin and eyes. Use impervious gloves and do not eat or drink when handling and administering the veterinary medicinal product. Wash hands or any exposed skin after use. In case of contact with eyes, wash immediately with clean running water, seek medical advice and show the package leaflet or the label to the physician. Persons developing a reaction after contact with the veterinary medicinal product should seek medical advice and avoid handling the veterinary medicinal product in future.

Special precautions for the protection of the environment:

Not applicable.

3.6. Adverse events

None known.

In cases of hypersensitivity reactions, treatment should be discontinued immediately.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to the marketing authorisation holder 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 rats and rabbits have not produced any evidence of a teratogenic effect.
The safety of the veterinary medicinal product has not been assessed during pregnancy and lactation. The use of the veterinary medicinal product is not recommended in pregnant and lactating mares.

3.8. Interaction with other medicinal products and other forms of interaction

Omeprazole may delay the elimination of warfarin. No other interaction with medicines routinely used in the treatment of horses is expected, although interaction with drugs metabolised by liver enzymes cannot be excluded.

3.9. Administration routes and dosage

Oral use.

Omeprazole is effective in horses of various breeds and under different management conditions; foals as young as four weeks of age and weighing over 70 kg; and breeding stallions.

Treatment of gastric ulcers: one administration per day during 28 consecutive days at the dose rate of 4 mg omeprazole per kg body weight (1 division of the oral syringe/50 kg BW) followed immediately by a

dosage regimen of one administration per day during 28 consecutive days at the dose rate of 1 mg omeprazole per kg body weight, to reduce the recurrence of gastric ulcers during treatment.
Should recurrence occur, re-treatment at a dose rate of 4 mg omeprazole per kg body weight (1 division of the oral syringe/50 kg BW) is recommended.
It is recommended to associate the treatment with changes of husbandry and training practices. Please see also the text under section 3.5

Prevention of gastric ulcers: one administration per day at the dose rate of 1 mg omeprazole per kg body weight.

To deliver omeprazole at the dose of 4 mg omeprazole/kg, set the oral syringe plunger to the appropriate dose division for the horse's weight. Each division on the oral syringe plunger delivers sufficient omeprazole to treat 50 kg body weight. The contents of one oral syringe will treat a 700 kg horse at the rate of 4 mg omeprazole per kg body weight.

To deliver omeprazole at the dose of 1 mg omeprazole /kg, set the oral syringe plunger to the dose division equivalent to one quarter of the horse's body weight. For example, to treat a horse weighing 400 kg, set the plunger to 100 kg. At this dose, each division on the oral syringe plunger will deliver sufficient omeprazole to treat 200 kg body weight.

Replace cap after use.

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

No undesirable effects related to treatment were observed following daily use for 91 days at omeprazole dosages up to 20 mg/kg in adult horses and in foals older than 2 months.

No undesirable effects related to treatment (in particular no adverse effect on the semen quality or reproductive behaviour) were observed following daily use for 71 days at an omeprazole dosage of 12 mg/kg in breeding stallions.

No undesirable effects related to treatment were observed following daily use for 21 days at a n omeprazole dosage of 40 mg/kg in adult horses.

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: 1 day
Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1. ATCVet code: QA02BC01

4.2. Pharmacodynamics

In studies lasting up to 28 days, treatment with omeprazole at the dose rate of 1 mg omeprazole per kg body weight per day has been shown to help prevent the occurrence of gastric ulcers in horses exposed to ulcerogenic conditions.

Omeprazole is a proton pump inhibitor belonging to the substituted benzimidazole class of compounds. It is an antacid, for treatment of peptic ulcers.

Omeprazole suppresses gastric acid secretion by specific inhibition of the H+/K+-ATPase enzyme system at the secretory surface of the parietal cell. The H+/K+- ATPase enzyme system is the acid (proton) pump within the gastric mucosa. Because H+/K+- ATPase is the final step involved in control of acid secretion, omeprazole blocks secretion irrespective of the stimulus. Omeprazole irreversibly binds to the gastric parietal cell H+/K+- ATPase enzyme that pumps hydrogen ions into the lumen of the stomach in exchange for potassium ions.

At 8, 16 and 24 hours after dosing horses with omeprazole at 4 mg/kg/day orally, pentagastrin-stimulated gastric acid secretion was inhibited by 99%, 95% and 90% and basal secretion was inhibited by 99%, 90% and 83%.

The full effect on the inhibition of acid secretion is reached by five days after the first administration.

4.3. Pharmacokinetics

The median bioavailability of omeprazole after oral administration as a paste is 10.5% (range 4.1 to 12.7%). The absorption is rapid with time to maximum plasma concentrations (T_{max}) of approximately 1.25 hours after dosing. C_{max} values for individual animals ranged between 121 ng/ml and 1470 ng/ml after one administration of the veterinary medicinal product at 4 mg/kg. There is a significant first-pass effect following oral administration. Omeprazole is rapidly metabolised principally into glucuronides of demethylated and hydroxylated omeprazole sulphide (urinary metabolites) and methyl sulphide omeprazole (biliary metabolite) as well as into reduced omeprazole (both).
After oral administration at 4 mg/kg, omeprazole is detectable in plasma for 9 hours after treatment and in urine as hydroxy omeprazole and O-desmethyl omeprazole at 24 hours but not at 48 hours. Omeprazole is eliminated quickly, mainly by urinary route (43 to 61% of the dose), and to a smaller extent by faecal route, with a terminal half-life ranging from approximately 0.5 to 8 hours.

After repeated oral administration, there is no evidence of accumulation.

5. PHARMACEUTICAL PARTICULARS

5.1. Major incompatibilities

Not applicable.

5.2. Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3. Special precautions for storage

Do not store above 30 °C.
Replace cap after use.

5.4. Nature and composition of immediate packaging

7 ml oral syringe containing 7.57 g of paste composed of polyethylene barrel, plunger and end cap, with polypropylene dosing rings.
Cartons of 1 or 7 oral syringes or buckets of 72 oral syringes.
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 material 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

7. MARKETING AUTHORISATION NUMBERS

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:

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

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 III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton Box & Bucket labelling

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Peptizole 370 mg/g Oral Paste

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each gram contains:
Active substance: Omeprazole 370 mg

3. PACKAGE SIZES

7.57 g
1 oral syringe
7 oral syringes
72 oral syringes

4. TARGET SPECIES

Horses

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 1 day.
Not authorised for use in animals producing milk for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 28 days.
Once opened, use by:…..

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 30 ^{o}C.
Replace cap after use.

10. THE WORDS "READ THE PACKAGE LEAFLET BEOFRE 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

14. MARKETINGAUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Oral Syringe labelling

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Peptizole

2. QUANTATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each gram contains: Omeprazole 370 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 28 days.
Once opened, use by:…..

ANNEX II
PACKAGE LEAFLET

PACKAGE LEAFLET:

1. Name of the veterinary medicinal product

Peptizole 370 mg/g Oral Paste for Horses

2. Composition

Each gram contains:
Active substance:
Omeprazole: 370 mg

Excipient:
Yellow Iron Oxide (E 172) 2 mg

A yellow to tan oily paste.

3. Target Species

Horses.

4. Indications for use

For treatment and prevention of gastric ulcers in horses.

5. Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special warnings:

The veterinarian should consider the need for performing relevant diagnostic tests before selection of the treatment dose rate.

Special precautions for safe use in the target species:

Not recommended for animals under 4 weeks of age or weighing less than 70 kg bodyweight. Stress (including high performance training and competition), feeding, management and husbandry practices may be associated with the development of gastric ulceration in horses. Individuals responsible for the well-being of horses should consider reducing the ulcerogenic challenge by modifying husbandry practices to achieve one or more of the following: reduced stress, reduced fasting, increased intake of roughage and access to grazing.

Special precautions to be taken by the person administrating the veterinary medicinal product to animals:
As the veterinary medicinal product may cause irritant and hypersensitivity reactions, avoid direct contact with skin and eyes. Use impervious gloves and do not eat or drink when handling and administering the veterinary medicinal product. Wash hands or any exposed skin after use. In case of contact with eyes, wash immediately with clean running water, seek medical advice and show the package leaflet or the label to the physician. Persons developing a reaction after contact with the veterinary medicinal product should seek medical advice and avoid handling the veterinary medicinal product in future.

Pregnancy and lactation:
Laboratory studies in rats and rabbits have not produced any evidence of a teratogenic effect.
The safety of the veterinary medicinal product has not been assessed during pregnancy and lactation. The use of this veterinary medicinal product is not recommended in pregnant and lactating mares.

Interaction with other medicinal products and other forms of interaction:
Omeprazole may delay the elimination of warfarin. No other interaction with medicines routinely used in the treatment of horses is expected, although interaction with drugs metabolised by liver enzymes cannot be excluded.

Overdose:
No undesirable effects related to treatment were observed following daily use for 91 days at omeprazole dosages up to 20 mg/kg in adult horses and in foals older than 2 months.

No undesirable effects related to treatment (in particular no adverse effect on the semen quality or reproductive behaviour) were observed following daily use for 71 days at an omeprazole dosage of 12 mg/kg in breeding stallions.

No undesirable effects related to treatment were observed following daily use for 21 days at an omeprazole dosage of 40 mg/kg in adult horses.

7. Adverse events

None known.

In cases of hypersensitivity reactions, treatment should be discontinued immediately.

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 reporting system}

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

Oral use.

Treatment of gastric ulcers: one administration per day during 28 consecutive days at the dose rate of 4 mg omeprazole per kg body weight (1 division of the oral syringe/50 kg BW) followed immediately by a dosage regimen of one administration per day during 28 consecutive days at the dose rate of 1 mg omeprazole per kg body weight, to reduce the recurrence of gastric ulcers during treatment.
Should recurrence occur, re-treatment at a dose rate of 4 mg omeprazole per kg body weight (1 division of the oral syringe/50 kg BW) is recommended.
It is recommended to associate the treatment with changes of husbandry and training practices. Please see also the text under special warnings.

Prevention of gastric ulcers: one administration per day at the dose rate of 1 mg omeprazole per kg body weight.

9. Advice on correct administration

Omeprazole is effective in horses of various breeds and under different management conditions; foals as young as four weeks of age and weighing over 70 kg; and breeding stallions.

To deliver omeprazole at the dose of 4 mg omeprazole/kg, set the oral syringe plunger to the appropriate dose division for the horse's weight. Each division on the oral syringe plunger delivers sufficient omeprazole to treat 50 kg body weight. The contents of one oral syringe will treat a 700 kg horse at the rate of 4 mg omeprazole per kg body weight.

To deliver omeprazole at the dose of 1 mg omeprazole/kg, set the oral syringe plunger to the dose division equivalent to one quarter of the horse's body weight. For example, to treat a horse weighing 400 kg, set the plunger to 100 kg. At this dose, each division on the oral syringe plunger will deliver sufficient omeprazole to treat 200 kg body weight.

Replace cap after use.

10. Withdrawal periods

Meat and offal: 1 day
Not authorised for use in animals producing milk for human consumption.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 30 ºC.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 28 days.
Replace cap after use.

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

7 ml oral syringe containing 7.57 g of paste composed of polyethylene barrel, plunger and end cap, with polypropylene dosing rings.
Cartons of 1 or 7 oral syringes or buckets of 72 oral syringes.

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 and contact details to report suspected adverse reactions:

[EU]
Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

[UK]
Norbrook Laboratories Limited
Station Works
Newry
Co. Down
BT35 6JP

Manufacturer responsible for batch release:
Norbrook Laboratories Limited
105 Armagh Road
Newry
Co. Down, BT35 6PU
United Kingdom

Norbrook Manufacturing Limited
Rossmore Industrial Estate
Monaghan
Ireland

17. Other information