PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> {Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EU Pharma Omeprazole 370 mg/g Oral Paste for Horses

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1g paste contains 370 mg of Omeprazole

3. PACKAGE SIZE

1 syringe,
7 syringes,
10 syringes,
14 syringes,
20 syringes,
56 syringes,
72 syringes

4. TARGET SPECIES

Horses

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

For oral use.

7. WITHDRAWAL PERIODS

Withdrawal Period:

Meat and offal: 1 day

Not authorised for use in mares producing milk for human consumption.

8. EXPIRY DATE

EXP {month/year}

Shelf life after opening the immediate packaging: 28 days.

Once opened, use by:

9. SPECIAL STORAGE PRECAUTIONS

Keep the container in the outer carton.

Do not store above 25ºC. Replace cap after use

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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co. Galway
H62 FH90
Ireland

14. MARKETING AUTHORISATION NUMBERS

Vm 08749/5114

15. BATCH NUMBER

BN {number}

16. SPECIAL WARNING(S), IF NECESSARY

None

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V ('To be supplied only on veterinary prescription')

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS {Label for Syringe}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EU Pharma Omeprazole 370 mg/g Oral Paste for Horses

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

Omeprazole 370 mg/g

3. BATCH NUMBER

BN {number}

4. EXPIRY DATE

EXP {month/year}

5. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EU Pharma Omeprazole 370 mg/g Oral Paste for Horses

2. COMPOSITION

1g gram paste contains:

Active substance:	Omeprazole:	370 mg
Excipients:	Ferric Oxide Yellow (E172):	2 mg

Smooth homogeneous yellow to yellow-tan paste.

3. TARGET SPECIES

Horses

4. INDICATIONS FOR USE

For treatment and prevention of gastric ulcers.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance or to any of the excipient(s).

6. SPECIAL WARNING(S)

For Animal Treatment Only

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 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. The product should not be used in animals under 4 weeks of age or weighing less than 75 kg bodyweight.

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

As this product may cause irritation and hypersensitivity reactions, avoid direct contact with skin and eyes.
People with known hypersensitivity to omeprazole and/or sesame should avoid contact with the veterinary medicinal product.
Personal protective equipment consisting of impervious gloves should be worn when handling the veterinary medicinal product.

Do not eat or drink when handling and administering the product.
Wash hands or any exposed skin after use.
The dosing syringe should be returned to the original packaging and suitably stored to prevent access by children.
In case of contact with eyes, wash immediately with clean running water and seek medical advice, and show the package leaflet or the label to the physician if symptoms persist.
Persons developing a reaction after contact with the product should avoid handling the 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 established during pregnancy and lactation in the target species. The use is not recommended during pregnancy and lactation.

Interactions with medicinal products and other forms of interaction:

Omeprazole may delay the elimination of warfarin. Omeprazole may potentially alter benzodiazepine metabolism and prolong CNS effects. Clarithromycin may increase levels of omeprazole. Omeprazole may reduce cyclosporine metabolism. Omeprazole may decrease absorption of drugs requiring decreased gastric pH for optimal absorption (ketoconazole, itraconazole, iron, ampicillin esters). 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.

Major incompatibilities:

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

7. ADVERSE EVENTS

None known.

Do not use in cases of hypersensitivity to the active substance or to any of the excipient(s).

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 EU Pharmaceuticals Ltd. Using the contact details at the end of this leaflet, or via the national reporting system.

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

Effective in horses of various breeds and under different management conditions; foals as young as four weeks of age and weighing over 75 kg; and breeding stallions.

For 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 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 is recommended.

It is recommended to associate the treatment with changes of husbandry and training practices. Please see also text under section 6 of the package leaflet.

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

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

9. ADVICE ON CORRECT ADMINISTRATION

To deliver the product at the dose of 4 mg omeprazole/kg, set the syringe plunger to the appropriate dose division for the horse’s weight. Each 100 kg dose division on the syringe plunger delivers sufficient omeprazole to treat 100 kg body weight. The contents of one syringe will treat a 700 kg horse at the rate of 4 mg omeprazole per kg body weight.

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

Replace cap after use.

Do not use EU Pharma Ltd 370 mg/g oral paste for horses if you notice a damaged syringe.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 1 day

Not authorised for use in mares producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25ºC. Replace cap after use.

Do not use this veterinary medicinal product after the expiry date which is stated on the label.

After first opening the immediate packaging use within 28 days

Once the immediate package is opened, using the shelf-life after first opening, calculate the discard date and record in the space provided on the label.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 08749/5114

Immediate package

Immediate packaging: Opaque white pre-filled oral syringe containing 7.57g of paste composed of

Barrel: Polyethylene LLDPE & HDPE

Barrel Cap: LDPE or LLDPE & HDPE

Plunger: Polypropylene

Ring: Polypropylene

Plastic Seal: LDPE

Package sizes

- Carton box of 1 syringe
- Carton box of 7 syringes
- Carton box of 10 syringes
- Carton box of 14 syringes

- Carton box of 20 syringes
- Carton box of 56 syringes
- Carton box of 72 syringes (bulk pack)

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co. Galway
H62 FH90
Ireland

Telephone: +353 (0)91 841788

vetpharmacoviggroup@chanellegroup.ie

17. OTHER INFORMATION

Not applicable.