ANNEX II

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Revozyn RTU 400 mg/ml suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
308.8 mg penethamate equivalent to 400 mg penethamate hydriodide

3. PACKAGE SIZE

50 ml

4. TARGET SPECIES

Cattle (lactating cows)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular administration.

7. WITHDRAWAL PERIODS

Withdrawal period:
Milk: 4 days.
Meat and offal: 10 days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days. Use by: _____/_____/_____

9. SPECIAL STORAGE PRECAUTIONS

Store below 30 °C.
Keep upright.

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

Eurovet Animal Health B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

14. MARKETING AUTHORISATION NUMBERS

Vm 16849/3000

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass vial 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Revozyn RTU

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each ml contains:
308.8 mg penethamate equivalent to 400 mg penethamate hydriodide

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use by: _____/_____/_____

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Revozyn RTU 400 mg/ml suspension for injection for cattle

2. Composition

Each ml contains:

Active substance:
308.8 mg penethamate equivalent to 400 mg penethamate hydriodide

A white to yellowish white, oily suspension.

3. Target species

Cattle (lactating cows)

4. Indications for use

For the treatment of clinical and subclinical mastitis in lactating cows caused by staphylococci and streptococci, susceptible to penicillin.

5. Contraindications

Do not use in cases of known hypersensitivity to the active substance, or to any of the excipients.
Do not administer by intravenous injection.

6. Special warnings

Special warnings:
Cross-resistance has been shown between benzylpenicillin and penicillins and beta-lactam antimicrobials in staphylococci and streptococci. Use of benzylpenicillin should be carefully considered when susceptibility testing has shown resistance to penicillins or beta-lactam antimicrobials because its effectiveness may be reduced.

Special precautions for safe use in the target species:
Use of the product should be based on identification and susceptibility testing of the target pathogens. If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.

Use of the product should be in accordance with official, national and regional antimicrobial policies.

The feeding of waste milk containing residues of penicillin to calves should be avoided up to the end of the milk withdrawal period (except during the colostral phase), because it could select antimicrobial-resistant bacteria (e.g. ESBL) within the intestinal microbiota of the calf and increase the faecal shedding of these bacteria.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product can cause sensitisation and contact dermatitis.
Hypersensitivity to penicillins may lead to cross reactions to cephalosporins, and *vice versa*.
Allergic reactions to these substances may occasionally be serious.
Handle this product with great care to avoid direct skin contact or self-injection.
People with known hypersensitivity to penicillin should avoid contact with the veterinary medicinal product.
Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product.
Wash hands after use.
In case of accidental contact with the skin, wash immediately with plenty of water. If symptoms following exposure such as skin rash develop or in case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes, or difficulty with breathing are more serious symptoms and require urgent medical attention.

Pregnancy and lactation:
Can be used during pregnancy or lactation.

Interaction with other medicinal products and other forms of interaction:
The veterinary medicinal product should not be administered concurrently with bacteriostatic antibiotics.

Overdose:
In case of overdose, no adverse effects other than those mentioned in section "Adverse events" are to be expected.

Special restrictions for use and special conditions for use:

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Cattle (lactating cows):
Very rare (<1 animal / 10,000 animals treated, including isolated reports): Urticaria, Anaphylactic shock[a], death[a]. Sensitisation against penicillins.
Undetermined frequency (cannot be estimated from the available data): Skin reactions (mild), such as dermatitis.
[a] Anaphylactic shock can be fatal, very rarely

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 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

For intramuscular administration only, preferably in the neck.
Administer alternately on the left and the right side.

Administer 10-15 mg penethamate hydriodide per kg body weight per day, once daily for 3 consecutive days, corresponding to 2.5-3.75 ml of the veterinary medicinal product per 100 kg body weight per day, once daily for 3 consecutive days.

9. Advice on correct administration

Shake well before use.

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

10. Withdrawal periods

Milk: 4 days.
Meat and offal: 10 days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store below 30 °C.
Keep upright.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 28 days.

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

Vm 16849/3000

Cardboard box with 1 x 50 ml vial.

15. Date on which the package leaflet was last revised

February 2023

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:

Eurovet Animal Health B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands
Tel: +31 (0)348-563434

Marketing authorisation holder:

Eurovet Animal Health B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

Manufacturer responsible for batch release:

Eurovet Animal Health B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

Produlab Pharma B.V.
Forellenweg 16
4941 SJ Raamsdonksveer
The Netherlands

Local representatives and contact details to report suspected adverse reactions:>

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

17. Other information

Approved 17 February 2023