

**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 for cattle  
Penethamate hydriodide

**2. STATEMENT OF ACTIVE SUBSTANCES**

1 ml suspension contains:

**Active substance:**

Penethamate hydriodide 400 mg

**3. PHARMACEUTICAL FORM**

Suspension for injection

**4. PACKAGE SIZE**

50 ml

**5. TARGET SPECIES**

Cattle (lactating cows)

**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Read the package leaflet before use.

**8. WITHDRAWAL PERIOD(S)**

Withdrawal period(s):

Milk: 4 days.

Meat and offal: 10 days.

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

Penicillins and cephalosporins may occasionally cause severe allergic reactions.

See package leaflet for user warnings.

**10. EXPIRY DATE**

EXP {month/year}

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

Once broached, use by: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

**11. SPECIAL STORAGE CONDITIONS**

Store below 30 °C.  
Keep upright.

**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**

Eurovet Animal Health BV  
Handelsweg 25  
5531 AE Bladel  
The Netherlands

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 16849/5000

**17. MANUFACTURER’S BATCH NUMBER**

Lot: {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

Vial 50 ml

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Revozyn RTU 400 mg/ml suspension for injection for cattle (lactating cows)  
Penethamate hydriodide

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

1 ml suspension contains:

**Active substance:**

Penethamate hydriodide 400 mg

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

50 ml

**4. ROUTE(S) OF ADMINISTRATION**

Read the package leaflet before use.

**5. WITHDRAWAL PERIOD(S)**

Withdrawal period(s):

Milk: 4 days.

Meat and offal: 10 days.

**6. BATCH NUMBER**

Lot:{number}

**7. EXPIRY DATE**

EXP: {month/year}

Once broached, use by: \_\_\_\_/\_\_\_\_/\_\_\_\_

**8. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

## **B. PACKAGE LEAFLET**

**PACKAGE LEAFLET:**  
Revozyn RTU 400 mg/ml  
Suspension for injection for cattle

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder:  
Eurovet Animal Health BV  
Handelsweg 25, 5531 AE Bladel  
The Netherlands

Manufacturer responsible for batch release:  
Eurovet Animal Health BV  
Handelsweg 25,  
5531 AE Bladel  
The Netherlands

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

Only the site testing and releasing the batches will be mentioned on the printed leaflet.

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Revozyn RTU 400 mg/ml suspension for injection for cattle  
Penethamate hydriodide

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

1 ml suspension contains:

**Active substance:**  
Penethamate hydriodide                      400 mg

A white to yellowish white oily suspension.

**4. INDICATION(S)**

Treatment of clinical and subclinical mastitis in lactating cows caused by staphylococci and streptococci, sensitive 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. ADVERSE REACTIONS**

The symptoms of adverse reactions range from mild skin reactions such as urticaria and dermatitis to severe reactions such as anaphylactic shock (very rarely, less than 1 animal in 10,000 animals treated) which very rarely may be fatal. In addition sensitisation against penicillins may occur.

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.

Alternatively you can report via your national reporting system {national system details}.

## **7. TARGET SPECIES**

Cattle (lactating cows).

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

Shake well before use.

Only for intramuscular administration, preferably in the neck.

Administer alternately on the left and the right side.

10,000-15,000 IU (10-15 mg penethamate hydriodide) per kg body weight per day, during 3 days, corresponding to 2.5-3.75 ml per 100 kg body weight per day, during 3 days.

## **9. ADVICE ON CORRECT ADMINISTRATION**

None.

## **10. WITHDRAWAL PERIOD(S)**

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 WARNING(S)**

Special precautions for use in animals:

Use of the veterinary medicinal product should be based on susceptibility testing of the bacteria isolated from the animal.

If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.



Official and local antimicrobial policies should be taken into account when the veterinary medicinal product is used.

Use of the veterinary medicinal product deviating from the instructions given in this leaflet may increase the prevalence of bacteria resistant to benzylpenicillin and may decrease the effectiveness of treatment with other beta-lactams due to the potential for cross-resistance.

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.

Direct skin contact or self-injection should be avoided. Gloves should be worn when handling the veterinary medicinal product.

Do not handle this veterinary medicinal product if you know you are sensitised, or if you have been advised not to work with such preparations.

Wash hands after use.

When the veterinary medicinal product comes into contact with the skin, wash immediately with plenty of water. If symptoms following exposure such as skin rash develop, or in the event of self-injection, you should seek medical advice and show the physician the package leaflet. 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:

Penicillins should not be administered concurrently with bacteriostatic antibiotics.

Overdose (symptoms, emergency procedures, antidotes):

In case of overdose, no adverse effects other than those mentioned in the 'Adverse reactions' section are to be expected.

Incompatibilities:

Do not mix with any other veterinary medicinal product.

**13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT 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.

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

April 2022

**15. OTHER INFORMATION**

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

Pack size: 50 ml.

Approved: 13 April 2022

