ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Penethaone 236.3 mg/ml powder and solvent for suspension for injection for cattle

penethamate hydriodide

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

"Powder vial: 5,000,000 IU (4726 mg) penethamate hydriodide
Solvent vial: 18 ml of a sterile solvent

Powder vial: 10,000,000 IU (9452 mg) penethamate hydriodide
Solvent vial: 36 ml of a sterile solvent

1 ml of the reconstituted suspension contains 250,000 IU (236.3 mg) of penethamate hydriodide."

3. PHARMACEUTICAL FORM

Powder and solvent for suspension for injection.

4. PACKAGE SIZE

5,000,000 IU powder vial and 18 ml solvent vial
5,000,000 IU powder vial and 18 ml solvent vial x 5
5,000,000 IU powder vial and 18 ml solvent vial x 10
10,000,000 IU powder vial and 36 ml solvent vial
10,000,000 IU powder vial and 36 ml solvent vial x 5
10,000,000 IU powder vial and 36 ml solvent vial x 10

5. TARGET SPECIES

Cattle (lactating cows)

6. INDICATION

7. METHOD AND ROUTE(S) OF ADMINISTRATION

IM
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal: 4 days
Milk: 2.5 days (60 hours).

9. SPECIAL WARNING(S), IF NECESSARY

'Penicillins and cephalosporins may occasionally cause severe allergic reactions.
See package leaflet for user warnings.
Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened, reconstitute immediately. Once reconstituted, use within 24h (2-8ºC)

11. SPECIAL STORAGE CONDITIONS

The reconstituted suspension can be stored in the refrigerator (2-8°C) for 24h.

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

Divasa-Farmavic, S.A.
Ctr. Sant Hipòlit, km 71
08503 Gurb-Vic (Barcelona)
Spain

16. MARKETING AUTHORISATION NUMBER(S)

Vm 33229/4004

17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

GLASS VIAL LABEL (POWDER)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Penethaone 236.3 mg/ml powder and solvent for suspension for injection for cattle

penethamate hydriodide

2. QUANTITY OF THE ACTIVE SUBSTANCE

Each vial contains 5,000,000 IU of penethamate hydriodide
Each vial contains 10,000,000 IU of penethamate hydriodide

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

5,000.000 IU
10,000,000 IU

4. ROUTE(S) OF ADMINISTRATION

IM
Read package leaflet before use.

5. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal: 4 days
Milk: 2.5 days (60 hours).

6. BATCH NUMBER

<Batch><Lot> {number}

7. EXPIRY DATE

EXP {month/year}
Once opened reconstitute immediately. Once reconstituted, use within 24h (2-8ºC).

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

GLASS VIAL LABEL (SOLVENT)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solvent for Penethaone 236.3 mg/ml powder and solvent for suspension for injection for cattle

2. QUANTITY OF THE ACTIVE SUBSTANCE

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

18 ml
36 ml

4. ROUTE(S) OF ADMINISTRATION

Read package leaflet before use.

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

<Batch><Lot> {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

Penethaone 236.3 mg/ml powder and solvent for 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 and manufacturer responsible for batch release:
Divasa-Farmavic S.A.
Ctra. Sant Hipòlit, km 71
08503 Gurb – Vic (Barcelona)
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Penethaone 236.3 mg/ml powder and solvent for suspension for injection for cattle

penethamate hydriodide

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

Powder and solvent for suspension for injection.
1 ml of the reconstituted suspension contains:

Active substance:
Penethamate hydriodide 236.3 mg (equivalent to 182.5 mg penethamate)
Equivalent to 250,000 IU of penethamate hydriodide

5,000,000 IU presentation
Powder vial contains 4.75 g of powder

Active substance:
Penethamate hydriodide 4726 mg (equivalent to 3649 mg of penethamate)
Equivalent to 5,000,000 IU of penethamate hydriodide

Excipient, q.s.f.

Solvent vial contains 18 ml
Excipients, q.s.f.

Total amount of reconstituted suspension 20 ml

10,000,000 IU presentation
Powder vial contains 9.50 g of powder

Active substance:
Penethamate hydriodide 9452 mg (equivalent to 7299 mg of penethamate)
Equivalent to 10,000,000 IU of penethamate hydriodide

Excipient, q.s.f.

Solvent vial contains 36 ml
Excipients, q.s.f.

Total amount of reconstituted suspension 40 ml

Powder and solvent for suspension for injection.
Powder vial: white-cream fine powder
Solvent vial: clear colourless solution
Reconstituted suspension: white-cream suspension

4. INDICATION

Treatment of mastitis in cattle caused by *Streptococcus uberis*, *Streptococcus dysgalactiae*, *Streptococcus agalactiae* and *Staphylococcus aureus* (beta-lactamase non-producing) , susceptible to penicillin.

5. CONTRAINDICATIONS

Do not use in cases of hipersensitivity to penicillins, cephalosporins, and/or any of the excipients.
Do not administer intravenously.
Do not use in lagomorphs and rodents such as guinea pigs, hamsters or gerbils..
Do not administer to animals with renal disease including anuria or oliguria.

6. ADVERSE REACTIONS

In very rare cases the symptoms of adverse reactions range from mild skin reactions such as urticaria and dermatitis to severe reactions such as anaphylactic shock with tremors, vomiting, salivation, gastrointestinal disorders and laryngeal oedema.

In some situations the treatment may lead to secondary infections due to overgrowth of non-target organisms.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

7. TARGET SPECIES

Cattle (lactating cows)

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

For deep intramuscular use.
Directions for use: Reconstitute the suspension using the entire contents of the solvent vial.

To provide the correct dose:

Use the powder vial, which contains penethamate hydriodide 5,000,000 IU with the solvent vial, which contains 18 ml of a sterile solvent.
Or alternatively, use the powder vial, which contains penethamate hydriodide 10,000,000 IU with the solvent vial, which contains 36 ml of a sterile solvent.

Shake well after reconstitution. A minimum of 10 inversions of vials can be necessary. Each ml of suspension contains 250,000 IU (236.3 mg) of penethamate hydriodide.

Dose: 15,000 IU (14.2 mg) of penethamate hydriodide per kg of body weight / day (equivalent to 6 ml of reconstituted medicinal product / 100 kg body weight) for up to four consecutive days. Shake well before use.
Administer the recommended daily dose every 24 hours, for three to four consecutive administrations.

The recommended maximum volume to be administered at a single injection site is 20 ml.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure administration of a correct dose, body weight should be determined as accurately as possible.

The stopper should not be punctured more than 10 times.

10. WITHDRAWAL PERIOD

Meat and offal: 4 days
Milk: 2.5 days (60 hours).

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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 This veterinary medicinal product does not require any special storage conditions.
Shelf life after reconstitution according to directions: 24 hours.
The reconstituted suspension should be stored in the refrigerator (2-8°C).

12. SPECIAL WARNING(S)

This veterinary medicinal product does not contain any antimicrobial preservative

Special precautions for use in animals:

Using penethamate hydriodide for the treatment of mastitis must be accompanied by hygienic measures to prevent reinfection.

Use of the 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.The veterinary medicinal product is not effective against beta-lactamase producing organisms.

Official national and regional antimicrobial policies should be taken into account when the product is used.

Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to benzylpenicillin and may decrease the effectiveness of treatment with other beta-lactam antimicrobials due to the potential for cross-resistance.

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

- Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross-reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.
- People with known hypersensitivity to penicillins, cephalosporins or any of the excipients should avoid contact with the veterinary medicinal product..
- Handle this product with great care to avoid exposure. Wear gloves when handling the veterinary medicinal product to avoid contact sensitization.
- In case of accidental self-injection or if you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the package leaflet or the label to the doctor. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.
- Wash hands after use.

Pregnancy:
Can be used during pregnancy.

Lactation:
Can be used during lactation
Interaction with other medicinal products and other forms of interaction:

The product should not be administered with antibiotics that have a bacteriostatic mode of action.
Anti-inflammatories such as salicylates, produce an increase in the elimination half-life of penetamate (iohydrate). In case of joint administration, adjust the dose of the antibacterial

Overdose (symptoms, emergency procedures, antidotes):

In cases of overdose, adverse reactions such as those described in Adverse reactions may occur.

Major incompatibilities:

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

For animal treament only.
To be supplied only on veterinary prescription

Pack sizes:
5,000,000 IU powder vial and 18 ml solvent vial
5,000,000 IU powder vial and 18 ml solvent vial x 5
5,000,000 IU powder vial and 18 ml solvent vial x 10
10,000,000 IU powder vial and 36 ml solvent vial
10,000,000 IU powder vial and 36 ml solvent vial x 5
10,000,000 IU powder vial and 36 ml solvent vial x 10

Not all pack sizes may be marketed.

Approved 14 May 2020