

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each powder vial contains:

Active substances:

Vials of 4.75 g:

Penethamate hydriodide 4726 mg
(equivalent to 3649 mg of penethamate)

Vials of 9.50 g:

Penethamate hydriodide 9452 mg
(equivalent to 7299 mg of penethamate)

Excipients:

Qualitative composition of excipients and other constituents (Powder vial)

Silica colloidal anhydrous

Each solvent vial (18 ml or 36 ml) contains:

Excipients:

Qualitative composition of excipients and other constituents (Solvent vial)
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Potassium dihydrogen phosphate (for pH adjustment)
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Sodium citrate (for pH adjustment)

Povidone

Water for injections

Each vial containing 4.75 and 9.50 g of powder is reconstituted with 18 ml and 36 ml of solvent to give suspension volumes of 20 ml and 40 ml, respectively. The final concentration is 236.3 mg/ml of penethamate hydriodide (equivalent to 182.5 mg/ml of penethamate).

Powder vial: white-cream fine powder

Solvent vial: clear colourless solution

3. CLINICAL INFORMATION

3.1 Target species

Cattle (lactating cows)

3.2 Indications for use for each target species

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

3.3 Contraindications

Do not use in cases of hypersensitivity 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 use in animals with renal disease including anuria or oliguria.

3.4 Special warnings

Treatment should be carried out during lactation.

3.5 Special precautions for use

This veterinary medicinal product does not contain any antimicrobial preservative.

Special precautions for safe use in the target species:

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 veterinary medicinal product is used.

Use of the veterinary medicinal 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 and / or cephalosporins should avoid contact with the veterinary medicinal product.

Handle this veterinary medicinal product with great care to avoid exposure.

Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product.

In case of accidental self-injection or if any symptoms following exposure such as a skin rash develop, 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.

Wash hands after use.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Cattle (lactating cows):

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Opportunistic infection ¹ Skin reaction ² (such as urticaria, dermatitis) Anaphylactic shock, tremor, vomiting, increased salivation, gastrointestinal disorder, laryngeal oedema
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¹ due to overgrowth of non-target organisms

² mild

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation

Can be used during pregnancy and lactation.

3.8 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.

3.9 Administration routes and dosage

Intramuscular use.

Administer by deep intramuscular injection.

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

Reconstituted suspension: white-cream suspension

To provide the correct dose:

Use the powder vial, which contains penethamate hydriodide 4726 mg with the solvent vial, which contains 18 ml of a sterile solvent.

Or alternatively, use the powder vial, which contains penethamate hydriodide 9452 mg 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 236.3 mg of penethamate hydriodide.

Dose: 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 three to four consecutive days. Shake well before use.

Administer the recommended daily dose every 24 hours, for three to four consecutive administrations.

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

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

The stopper should not be punctured more than 10 times.

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

In cases of overdose, adverse reactions such as those described in Section 3.6 may occur.

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

For administration only by a veterinarian.

3.12 Withdrawal periods

Meat and offal: 4 days

Milk: 60 hours

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01CE90

4.2 Pharmacodynamics

The active substance, penethamate hydriodide, is a prodrug which releases benzylpenicillin.

Chemically, it is a diethylaminoethanol ester of penicillin.

Mode of action:

Benzylpenicillin works by blocking the biosynthesis of the bacterial cell wall.

Benzylpenicillin covalently attaches to and subsequently inactivates penicillin-binding proteins (PBPs), which are located on the inner surface of the bacterial membrane.

The PBPs (transpeptidase, carboxypeptidases, endopeptidases) are enzymes involved in the terminal stages of bacterial cell-wall synthesis.

Penicillins are only active against bacteria in the multiplication phase, so its activity is primarily bactericidal and time-dependent.

The antimicrobial spectrum of the active substance corresponds to that of benzylpenicillin which is effective against beta-lactamase negative *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus uberis* and *Staphylococcus aureus*.

Mechanisms of resistance:

The most frequent mechanism is producing beta-lactamases (more specifically penicillinase especially in *S. aureus*), which break the beta-lactam ring of penicillins making them inactive.

4.3 Pharmacokinetics

Following intramuscular administration to dairy cows, C_{max} is rapidly achieved in blood and milk (3 and 7 hours respectively). Ninety percent of the antibiotic is hydrolysed in blood and 98% in milk. As a result of hydrolysis, diethylaminoethanol and benzylpenicillin are produced, with the latter being the therapeutically active molecule. The distribution is rapid within the organism, with particular affinity

for lung and mammary gland tissues. It crosses the placenta and enters the foetal circulation slowly.

5. PHARMACEUTICAL PARTICULARS

5.1 Major Incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.

Shelf life after reconstitution according to directions: 24 hours.

5.3 Special precautions for storage

Before reconstitution, the powder and solvent vials do not require any special storage conditions.

Store the reconstituted product in a refrigerator (2 °C – 8 °C).

5.4 Nature and composition of immediate packaging

Carton box containing either:

Vials of 4.75 g of powder and 18 ml of solvent:

Powder vial: 25 ml type I colourless glass vial closed with a bromobutyl stopper and sealed with an aluminium flip-top seal

Solvent vial: 20 ml type II colourless glass vial closed with a bromobutyl stopper and sealed with an aluminium flip-top seal

or

Vials of 9.50 g of powder and 36 ml of solvent:

Powder vial: 50 ml type II colourless glass vial closed with a bromobutyl stopper and sealed with an aluminium flip-top seal.

Solvent vial: 50 ml type II colourless glass vial closed with a bromobutyl stopper and sealed with an aluminium flip-top seal

Pack sizes:

Cartonboard box with 1 x 4.75 g powder vial and 1 x 18 ml solvent vial

Cartonboard box with 5 x 4.75 g powder vials and 5 x 18 ml solvent vials

Cartonboard box with 10 x 4.75 g powder vials and 10 x 18 ml solvent vials

Cartonboard box with 1 x 9.50 g powder vial and 1 x 36 ml solvent vial

Cartonboard box with 5 x 9.50 g powder vials and 5 x 36 ml solvent vials

Cartonboard box with 10 x 9.50 g powder vials and 10 x 36 ml solvent vials

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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 materials 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

Divasa-Farmavic S.A.

7. MARKETING AUTHORISATION NUMBER

Vm 33229/4004

8. DATE OF FIRST AUTHORISATION

04 August 2015

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

June 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

Gavin Hall

Approved: 22 July 2026