

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Mamyzin 269.5 mg/ml Powder and Solvent for Suspension for Injection for cattle

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5g vial contains:

Penethamate hydriodide 5 million IU

Each 10 g vial contains:

Penethamate hydriodide 10 million IU

Each 15ml and 30ml vial of solvent contains:

Methyl parahydroxybenzoate, as preservative 1.5mg/ml

Each ml of the reconstituted product contains 269.5 mg of penethamate hydriodide.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Powder and solvent for suspension for injection

Powder vial: White to off-white crystalline powder

Solvent Vial: Clear solution

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, dairy

4.2 Indications for use, specifying the target species

Bovine mastitis caused by penicillin sensitive organisms.

4.3 Contraindications

Do not use in animals known to be hypersensitive to penicillin.

Do not administer by intravenous injection.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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. 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-lactams due to the potential for cross-resistance.

Special precautions to be taken by the person administering the veterinary 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.

1. Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.
2. Handle the product with great care to avoid exposure, taking all recommended precautions.
3. If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty breathing are more serious symptoms and require urgent medical attention.

Wash hands after use. In the event of self-administration seek medical advice

4.6 Adverse reactions (frequency and seriousness)

In very rare cases anaphylactic shock may occur, which can be fatal.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy.

4.8 Interaction with other medicinal products and other forms of interactions

Penicillins should not be administered concurrently with bacteriostatic antibiotics.

4.9 Amounts to be administered and administration route

Reconstitution: Reconstitute the suspension using the entire contents of the 5 g vial with the 15 ml vial of diluent OR the 10 g vial with the 30 ml vial of diluent provided.

Use only 5 g vial with 15 ml diluent and 10 g vial with 30 ml diluent to provide the correct dose.

Shake well after reconstitution.

Dosage: The daily dose is 15 mg penethamate hydriodide per kg bodyweight for 3 consecutive days. This is equivalent to 5.5 ml of the reconstituted suspension per 100 kg bodyweight.

Shake well before administration.

For intramuscular use. Do not administer intravenously.

To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid under-dosing.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Penicillins have a very wide margin of safety.

4.11 Withdrawal period(s)

Cattle meat and offal: 7 days

Cattle milk: 96 hours

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Vet code: QJ10CE90: Beta lactamase sensitive penicillins.

5.1 Pharmacodynamic properties

Its mode of action is by prevention of cell wall synthesis during bacterial cell growth and is primarily bactericidal. The in-vitro spectrum of activity is mainly within the gram-positive class of bacteria eg *Staphylococcus* spp, *Streptococcus* spp, *Clostridium* spp, *Bacillus* spp etc.

5.2 Pharmacokinetic particulars

Penethamate hydriodide is a prodrug which releases benzylpenicillin quantitatively at hydrolysis. The pKa-value of penethamate hydriodide is 8.4. This means that in aqueous solution at physiological pH of 7.2, 8.2% of the drug will be present as the uncharged molecule while 91.8% will be present as the ion. In aqueous solution penethamate is hydrolysed to form benzylpenicillin and diethylaminoethanol. After

intramuscular injection the prodrug itself as well as the released alcohol, diethylaminoethanol has not shown any unexpected pharmacological effects.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate
Water for injections
Egg lecithin
Sodium citrate anhydrous
Polysorbate 81

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after reconstitution according to directions: Use immediately.

6.4 Special precautions for storage

Do not store above 25°C.
Discard unused suspension.
Keep the container in the outer carton.

6.5 Nature and composition of immediate packaging

Colourless, Type I Ph Eur glass vials, closed with butyl rubber stoppers and metal caps containing 5 or 10 g of penethamate hydriodide and 15 or 30 ml solvent to produce a reconstituted suspension.

Pack sizes:

10g vials and 30ml solvent x 10
5g vials and 15ml solvent x 10
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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

7 MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA10454/009/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd March 2000
Date of last renewal: 22nd August 2009

10 DATE OF REVISION OF THE TEXT

November 2018