

- 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 skin rash, you should seek medical advice and show the doctor this warning.  
Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Wash hands after use.

In the event of self-administration seek medical advice.

FOR ANIMAL TREATMENT ONLY.  
KEEP OUT OF REACH OF CHILDREN.

#### Pharmaceutical precautions

Do not store above 25°C.

After reconstitution, use immediately. Discard unused suspension.

Unused product and containers should be disposed of in accordance with national requirements.

#### Legal category

[POM] Prescription Only Medicine

#### Package information

Boxes of 10 vials of penethamate hydriodide powder and 10 vials of solution for reconstitution.

#### Further information

Nil

#### Marketing authorisation numbers

GB: VM 00015/4062

IRL: VPA 10007/36/1

#### Marketing authorization holder

Boehringer Ingelheim Limited  
Ellesfield Avenue  
Bracknell  
Berkshire  
RG12 8YS  
UK  
Tel.: +44(0) 1344 424600

Manufacturer: Leo Laboratories Limited  
Cashel Road, Dublin

#### Date of Preparation

November 2003

## Mamyzin® injection

## Data Sheet

V

#### Presentation

Vial containing 5 g or 10 g Penethamate hydriodide powder. A second vial contains 15 ml or 30 ml sterile diluent containing 1.5 mg per ml methylparahydroxybenzoate Ph Eur as preservative.

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

#### Uses

For the treatment of mastitis in dairy cows caused by penicillin sensitive organisms.

Penethamate hydriodide is a prodrug which releases benzyl penicillin on hydrolysis. It is an antibacterial agent with a wide spectrum of activity. The in-vitro spectrum of activity is mainly within the Gram-positive class of bacteria e.g. *Staphylococcus spp.*, *Streptococcus spp.*, *Clostridium spp.*, *Bacillus spp.*

#### Dosage and Administration

**Reconstitution:** Reconstitute the suspension using the entire contents of the 5 g vial and 15 ml vial of diluent provided OR the 10 g vial and 30 ml vial of diluent provided. Shake well after reconstitution.

**Dosage:** The dose is 10–15 mg Penethamate hydriodide per kg bodyweight. This is equivalent to 3.5–5.5 ml of the reconstituted suspension per 100 kg bodyweight. Shake well before administration.

The injection can be repeated at intervals of 24 hours for up to 4 days in total. For intramuscular use only. Do not administer intravenously.

#### Contra-indications, warnings, etc

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

Do not administer by intravenous injection.

Can be used during pregnancy.

Should not be administered concurrently with bacteriostatic antibiotics.

#### Withdrawal periods

Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 7 days from the last treatment.

Milk for human consumption must not be taken from cows during treatment. Milk for human consumption may only be taken 72 hours from the last treatment.

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.