PARTICULARS TO APPEAR ON THE OUTER PACKAGE: Carton, 10 vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Mamyzin 269.5 mg/ml Powder and solvent for suspension for injection for cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 10g vial contains:
Penethamate hydriodide 10 million IU
Each 30ml vial of solvent contains:
methyl parahydroxybenzoate, as preservative 1.5mg/ml
Each ml of the reconstituted product contains 269.5mg of penethamate hydriodide.

3. PHARMACEUTICAL FORM

Powder and solvent for suspension for injection

4. PACKAGE SIZE

10 vials of powder each containing 10 g Penethamate hydriodide with 10 vials of solution for reconstitution containing 30 ml Water for Injections with 1.5 mg per ml methylparahydroxybenzoate as preservative

5. TARGET SPECIES

For use in milking cattle.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular injection only.

8. WITHDRAWAL PERIOD

Cattle meat and offal: 7 days
Cattle milk: 96 hours

9. SPECIAL WARNING(S), IF NECESSARY

For directions, uses, dosage, recommendations, contra-indications, warnings and disposal advice etc., see leaflet.
After reconstitution, use immediately. Discard unused suspension.
Avoid the introduction of contamination during use.

10. EXPIRY DATE

Expiry Date:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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.

POM-V UK

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

KEEP OUT OF REACH AND SIGHT OF CHILDREN.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4298

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

18. OTHER INFORMATION

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS: Vial containing 10 g Penethamate hydriodide 10 million IU

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Mamyzin 269.5mg/ml Powder for suspension for injection for cattle

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each 10g vial contains: Penethamate hydriodide 10 million IU
Each 30ml vial of solvent contains: methyl parahydroxybenzoate, as preservative 1.5mg/ml
Each ml of the reconstituted product contains 269.5mg of penethamate hydriodide.

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

10 g

4. ROUTE(S) OF ADMINISTRATION

For intramuscular injection only.

5. WITHDRAWAL PERIOD

Cattle meat and offal: 7 days
Cattle milk: 96 hours

6. BATCH NUMBER

Batch No.:

7. EXPIRY DATE

Expiry Date:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

FOR ANIMAL TREATMENT ONLY

.9. OTHER INFORMATION

For use in cattle only.

KEEP OUT OF REACH AND SIGHT OF CHILDREN.

To be reconstituted with 30 ml of solvent supplied.

Avoid the introduction of contamination during use.

For directions, dosage recommendations, contraindications, warnings, disposal advice etc, see leaflet.
Do not store above 25° C.
After reconstitution, use immediately.
Discard unused suspension.
Keep the container in the outer carton.

Vm 08327/4298

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

POM-V UK

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS: Solvent (for use with Mamyzin® only)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Mamyzin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Water for Injections with 1.5 mg per ml methylparahydroxybenzoate as preservative

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

30 ml

4. ROUTE(S) OF ADMINISTRATION

For intramuscular injection only.

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Batch No.:

7. EXPIRY DATE

Expiry Date:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

FOR ANIMAL TREATMENT ONLY

.9. OTHER INFORMATION

For use in the reconstitution of Mamyzin® Injection for cattle.
Use entire contents of this vial.
KEEP OUT OF REACH AND SIGHT OF CHILDREN.
Do not store above 25° C.
Keep the container in the outer carton.

Vm 08327/4298

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

PACKAGE LEAFLET

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

Marketing authorization holder
Boehringer Ingelheim Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

Manufacturer responsible for batch release:
Lohmann Pharma Herstellung GmbH
27472 Cuxhaven
Germany

Haupt Pharma Latina S.r.l
04100 Borgo San Michele - Latina
Italy

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Mamyzin 269.5mg/ml powder and solvent for suspension for injection for cattle

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

Presentation
Powder and solvent for suspension for Injection
Each 5g vial contains:
Penethamate hydriodide 5 million IU
Each 10g vial contains:
Penethamate hydriodide 10 million IU
Each 15ml and 30ml vial of solvent contains: methyl parahydroxybenzoate, as preservative 1.5 mg/ml
Use only 5 g vial with 15 ml solvent and 10 g vial with 30 ml solvent to provide the correct dose.
Each ml of the reconstituted product contains 269.5mg of penethamate hydriodide

4. INDICATION(S)

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

5. CONTRAINDICATIONS

Do not use in animals known to be hypersensitive to penicillin.
Do not administer by intravenous injection.

6. ADVERSE REACTIONS

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

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.

7. TARGET SPECIES

Dairy cows

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

Dosage and Administration
Reconstitution: Reconstitute the suspension using the entire contents of the 5 g vial and 15 ml vial of solvent provided OR the 10 g vial and 30 ml vial of solvent provided. Use only 5 g vial with 15 ml solvent and 10 g vial with 30 ml solvent to provide the correct dose. Shake well after reconstitution.
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 only. Do not administer intravenously.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD(S)

Cattle meat and offal: 7 days
Cattle milk: 96 hours

11. SPECIAL STORAGE PRECAUTIONS

Pharmaceutical precautions
Do not store above 25°C.
Do not use after the expiry date stated on the label/carton.
After reconstitution, use immediately.
Discard unused suspension.

12. SPECIAL WARNING(S)

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 Package 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 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.
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-injection seek medical advice.

Use during pregnancy, lactation or lay
Can be used during pregnancy.

Interaction with other medicinal products and other forms of interaction
Penicillins should not be administered concurrently with bacteriostatic antibiotics.

Overdose (symptoms, emergency procedures, antidotes), if necessary
Penicillins have a very wide margin of safety.

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

Disposal Advice
Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Date on which package leaflet was last prepared: May 2017

15. OTHER INFORMATION

UK POM-V
Vm Holder: Boehringer Ingelheim Animal Health UK Ltd.

FOR ANIMAL TREATMENT ONLY.
KEEP OUT OF REACH AND SIGHT OF CHILDREN. To be supplied only on veterinary prescription.
Package information

Boxes of 10 vials of penethamate hydriodide powder and 10 vials of solution for reconstitution.
Pack sizes:
10g vials and 30ml solvent x 10
5g vials and 15ml solvent x 10
Not all pack sizes may be marketed.

Further information
Nil.

Marketing Authorisation numbers
UK: Vm 08327/4298
Mamyzin® is a registered trademark of Boehringer Ingelheim Vetmedica GmbH, used under licence.

Approved 02 October 2019