LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
{Carton box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Novomate 277.8 mg/ml powder and solvent for suspension for injection for cattle

Penethamate hydriodide

2. STATEMENT OF ACTIVE SUBSTANCES

Powder vial contains:
Active substance:
Each 5 g vial contains:
Penethamate hydriodide: 5 g (equivalent to 3.86 g penethamate)

Each 10 g vial contains:
Penethamate hydriodide: 10 g (equivalent to 7.72 g penethamate)

Each ml of the reconstituted product contains:
Active substance:
Penethamate hydriodide: 277.8 mg (equivalent to 214.50 mg)

3. PHARMACEUTICAL FORM

Powder and solvent for suspension for injection.

4. PACKAGE SIZE

5 g vial and 15 ml solvent
(2 x) 5 g vial and (2 x) 15 ml solvent
(6 x) 5 g vial and (6 x) 15 ml solvent
10 g vial and 30 ml solvent
(2 x) 10 g vial and (2 x) 30 ml solvent
(6 x) 10 g vial and (6 x) 30 ml solvent

5. TARGET SPECIES

Cattle (lactating cows)

6. INDICATION(S)

Read the package leaflet before use

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular use after reconstitution.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:

Meat and offal: 10 days
Milk: 96 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

Shelf life after reconstitution:

Storage in refrigerator (2°C – 8°C)	7 days
Storage below 25°C	2 days

EXP {month/year}
Once opened use by…

11. SPECIAL STORAGE CONDITIONS

Powder and Solvent:
This veterinary medicinal product does not require any special storage conditions.

Reconstituted product:
Store the reconstituted product in the outer carton in order to protect from light.
Store the reconstituted product in a refrigerator (2°C – 8°C) or below 25°C.

12. SPECIFIC 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

Lohmann Pharma Herstellung GmbH
Heinz-Lohmann-Strasse 5
27472 Cuxhaven
Germany

16. MARKETING AUTHORISATION NUMBER(S)

Vm 52429/4000

17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial - powder

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Novomate 277.8 mg/ml powder and solvent for suspension for injection for cattle

Penethamate hydriodide

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Active substance:
1 g powder contains:
Penethamate hydriodide 1 g

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

5 g
10 g

4. ROUTE(S) OF ADMINISTRATION

For intramuscular use after reconstitution with 15 ml (30 ml) solvent

5. WITHDRAWAL PERIOD

Withdrawal period:

Meat and offal: 10 days
Milk: 96 hours

6. BATCH NUMBER

Batch Lot

7. EXPIRY DATE

Shelf life after reconstitution:
In refrigerator (2°C – 8°C): 7 days
Storage below 25°C 2 days

EXP {month/year}
Once opened use by…

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial Solvent

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Novomate 277.8 mg/ml powder and solvent for suspension for injection for cattle

Penethamate hydriodide

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

15 ml
30 ml

4. ROUTE(S) OF ADMINISTRATION

For intramuscular use after reconstitution

5. WITHDRAWAL PERIOD

Withdrawal period:

Meat and offal: 10 days
Milk: 96 hours

6. BATCH NUMBER

Batch Lot

7. EXPIRY DATE

EXP {month/year}
Once opened use immediately to reconstitute powder (5 g) (10 g) then discard remainder….

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

Novomate 277.8 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:
Lohmann Pharma Herstellung GmbH
Heinz-Lohmann-Strasse 5
27472 Cuxhaven
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Novomate 277.8 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.

Powder vial contains:
Active substance:
Each 5 g vial contains:
Penethamate hydriodide: 5 g (equivalent to 3.86 g penethamate)

Each 10 g vial contains:
Penethamate hydriodide: 10 g (equivalent to 7.72 g penethamate)

Solvent vial contains (15 ml or 30 ml of a sterile solvent):
Excipients:
Methyl parahydroxybenzoate (E218): 1.8 mg/ml
Propyl parahydroxybenzoate: 0.18 mg/ml

Each ml of the reconstituted product contains:
Active substance:
Penethamate hydriodide: 277.8 mg (equivalent to 214.50 mg)

Powder vial: White to slightly yellow powder
Solvent vial: Clear, colourless solution
The reconstituted suspension is of white to slightly yellow colour.

4. INDICATION(S)

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

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to penicillins, cephalosporins, and/or any of the excipients.
Do not administer intravenously.
Do not administer to animals with renal disease including anuria or oliguria.

6. ADVERSE REACTIONS

Animals may experience discomfort or pain upon administration of the product.
Minimal swelling, which should resolve without treatment, may be observed at the injection site after administration of the product.
In very rare cases anaphylactic shock may occur, which can be fatal.

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).>

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.

Alternatively, you can report via your national reporting system.

7. TARGET SPECIES

Cattle (lactating cows)

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

For intramuscular use.

Reconstitution:

Reconstitute the suspension by using a suitably scaled syringe to add exactly 15 ml solvent to the contents of the 5 g powder vial OR exactly 30 ml solvent to the contents of the 10 g powder vial, giving reconstituted volumes of 18 ml and 36 ml respectively. Once broached, the solvent vial with any residual solvent must be discarded.

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 and before each use.

Dosage: The dose is 15 mg penethamate hydriodide per kg bodyweight.
This is equivalent to 5.4 ml of the reconstituted suspension per 100 kg bodyweight.
Shake well before administration.

The injection should be repeated with a time interval of 24 hours for 4 consecutive days in total.
The injection site volume should not exceed a maximum of 20 ml per injection site.

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

9. ADVICE ON CORRECT ADMINISTRATION

Shake well after reconstitution and before each use, a white to slighty yellow suspension forms.

10. WITHDRAWAL PERIOD

Meat and offal: 10 days
Milk: 96 hours

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Powder and Solvent:
This veterinary medicinal product does not require any special storage conditions.

Reconstituted product:
Store the reconstituted product the outer carton in order to protect from light.
Store the reconstituted product in a refrigerator (2°C – 8°C): or below 25°C.

Do not use this veterinary medicinal product after the expiry date which is stated on the label.
This expiry date refers to the last day of that month.

Shelf life after reconstitution according to directions:
Storage in refrigerator (2°C – 8°C): 7 days
Storage below 25°C: 2 days

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 and local 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.

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

The feeding of waste milk containing penicillin residues to calves should be avoided up to the end of the milk withdrawal period (except during the colostral phase), because it could select antimicrobial-resistant bacteria within the intestinal microbiota of the calf and increase the faecal shedding of these bacteria.

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.

Do not handle this product if you know you are sensitised to penicillins or any of the excipients, or if you have been advised not to work with such preparations.Handle the product with great care to avoid exposure, taking all recommended precautions.

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.
Care should be taken to avoid accidental self-injection and contact with the eyes. In case of accidental self-injection, seek medical advice immediately.

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:

Penicillins should not be administered concurrently with bacteriostatic antibiotics.

Overdose (symptoms, emergency procedures, antidotes):

Penicillins have a very wide margin of safety.

Incompatibilities:

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

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

March 2021

15. OTHER INFORMATION

Pack sizes:
5 g vial and 15 ml solvent
(2 x) 5 g vial and 15 ml solvent
(6 x) 5 g vial and 15 ml solvent
10 g vial and 30 ml solvent
(2 x) 10 g vial and 30 ml solvent
(6 x) 10 g vial and 30 ml solvent

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved 07 June 2021