PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box with 24 intramammary syringes
Cardboard box with 20 intramammary syringes
Cardboard box with 10 intramammary syringes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Novocillin LC 1000 mg intramammary suspension for lactating cows

Oxacillin sodium

2. STATEMENT OF ACTIVE SUBSTANCES

Each intramammary syringe of 10 g contains:

Active substance:
Oxacillin sodium 1000 mg
(equivalent to 1042.5 mg Oxacillin sodium monohydrate or 948 mg oxacillin)

3. PHARMACEUTICAL FORM

Intramammary suspension

4. PACKAGE SIZE

10 intramammary syringes containing 10 g suspension each
20 intramammary syringes containing 10 g suspension each
24 intramammary syringes containing 10 g suspension each

5. TARGET SPECIES

Cattle (lactating cows)

6. INDICATION(S)

[Not applicable]

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramammary use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:

Meat and offal	6 days
Milk	144 hours (6 days)

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

EXP {month/year}
Once opened use immediately.

11. SPECIAL STORAGE CONDITIONS

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

Pharmanovo Veterinärarzneimittel GmbH
Liebochstr. 9
8143 Dobl
Austria

16. MARKETING AUTHORISATION NUMBER(S)

Vm 52644/3000

17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Intramammary syringe 10 g

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Novocillin LC 1000 mg intramammary suspension for lactating cows

Oxacillin sodium

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each intramammary syringe of 10 g contains:

Active substance:
Oxacillin sodium 1000 mg
(equivalent to 1042.5 mg Oxacillin sodium monohydrate or 948 mg oxacillin)

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

10 g

4. ROUTE(S) OF ADMINISTRATION

Intramammary use

5. WITHDRAWAL PERIOD(S)

Withdrawal periods:

Meat and offal	6 days
Milk	144 hours (6 days)

6. BATCH NUMBER

<Batch><Lot> {number}

7. EXPIRY DATE

EXP {month/year}
Once opened use immediately.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE LEAFLET

Novocillin LC 1000 mg intramammary suspension for lactating cows

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

Marketing authorisation holder:

Pharmanovo Veterinararzneimittel GmbH
Liebochstrasse 9
Dobl
Dobl-Zwaring
Steiermark
A-8143
Austria

Manufacturer responsible for batch release:

Produlab Pharma B.V.
Forellenweg 16
4941 SJ Raamsdonksveer
The Netherlands

Vet-Agro Multi-Trade Company Sp. z o.o.
Gliniana 32
20-616 Lublin
Poland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Novocillin LC 1000 mg intramammary suspension for lactating cows
Oxacillin sodium

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

Each intramammary syringe of 10 g contains:

Active substance:
Oxacillin sodium 1000 mg
(equivalent to 1042.5 mg Oxacillin sodium monohydrate or 948 mg oxacillin)

White to almost white suspension.

4. INDICATION(S)

Treatment of clinical mastitis caused *Staphylococcus* spp. (including β-lactamase producing strains) and *Streptococcus* spp. susceptible to oxacillin.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance, penicillin, cephalosporin or to any of the excipients.
Do not use in case of resistance to isoxazolyl penicillins and cephalosporins.

6. ADVERSE REACTIONS

Hypersensitivity reactions (i.e., allergic skin reactions, anaphylaxis) have been reported very rarely in spontaneous reports. If such a reaction occurs, the current treatment should be stopped immediately and an appropriate symptomatic treatment be initiated.
In case of anaphylaxis: adrenaline (epinephrine) and glucocorticoids i.v.
In case of allergic skin reactions: antihistamines and/or glucocorticoids.

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 {national system details}.

7. TARGET SPECIES

Cattle (lactating cows)

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

For intramammary use.

1000 mg oxacillin sodium per affected udder quarter, corresponding to 10 g of the product (full content of one syringe) per affected udder quarter. Three consecutive treatments must be administered, at 24-hour intervals.

Immediately prior to the individual treatment, all udder quarters should be milked out carefully. The teat tip should be cleaned and disinfected, followed by intramammary administration of the content from one intramammary syringe per affected udder quarter.

If no significant improvement of the clinical condition is observed within 2 days of treatment, the diagnosis should be reviewed.

Shake the product before use.

9. ADVICE ON CORRECT ADMINISTRATION

Not applicable.

10. WITHDRAWAL PERIOD(S)

Meat and offal	6 days
Milk	144 hours (6 days)

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

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

Shelf life after first opening the immediate packaging: use immediately.

12. SPECIAL WARNING(S)

Special warnings for each target species:
None.

Special precautions for use in animals
In the case of severe swelling of the udder quarter, obstructive swelling of the milk duct and/or obstruction of the milk ducts by cell of detritus, the veterinary medicinal product must be administered with caution to avoid pain and injuries of the teat canal.
Use of the product should be based on identification and susceptibility testing of the target pathogens. If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target bacteria at farm level, or at local/regional level.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to oxacillin and may decrease the effectiveness of the treatment.
Use of the product should be in accordance with official, national and regional antimicrobial policies.
The feeding of waste milk containing residues of oxacillin 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 penicillin 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 cephalosporins or if you have been advised not to work with such preparations.
Handle this product with great care to avoid exposure by accidental contact with the skin or eyes. Persons developing a reaction after contact with the product should avoid handling the product (and other penicillin and cephalosporin containing products) in future.
It is recommended to wear gloves when handling or administering the product. Wash exposed skin after use. In case of any eye contact, wash the eyes thoroughly with copious amounts of clean running water.
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.

Pregnancy and lactation:
Novocillin LC is intended for use during lactation.

Interaction with other medicinal products and other forms of interaction:
Regarding antibacterial effects, a potential antagonism exists between penicillins and chemotherapeutic agents with rapid bacteriostatic action (tetracyclines, macrolides, lincosamides).

Overdose (symptoms, emergency procedures, antidotes):
No information available.

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

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

February 2022

15. OTHER INFORMATION

Pack sizes:
Package with 10 intramammary syringes containing 10 g suspension each
Package with 20 intramammary syringes containing 10 g suspension each
Package with 24 intramammary syringes containing 10 g suspension each

Not all pack sizes may be marketed.

Approved: 07 April 2022