ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

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

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. PACKAGE SIZE

10 x 10 g
20 x 10 g
24 x 10 g

4. TARGET SPECIES

Cattle (lactating cows)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramammary use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 6 days.
Milk: 144 hours (6 days).

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Pharmanovo Veterinararzneimittel GmbH

14. MARKETING AUTHORISATION NUMBERS

Vm 52644/3000

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Intramammary syringe 10 g

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Novocillin LC

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1000 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Novocillin LC 1000 mg intramammary suspension for lactating cows

2. Composition

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.

3. Target species

Cattle (lactating cows)

4. Indications for use

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. Special warnings

Special precautions for safe use in the target species:
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 detritus, the veterinary medicinal product must be administered with caution to avoid pain and injuries of the teat canal.
Use of the veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal 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.
People with known hypersensitivity to penicillins or cephalosporins should avoid contact with the veterinary medicinal product.
Handle this veterinary medicinal product with great care to avoid exposure by accidental contact with the skin or eyes.
Persons developing a reaction after contact with the veterinary medicinal product should avoid contact (and other penicillin and cephalosporin containing medicinal products) in future.
Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product. Wash exposed skin after use. In case of any eye contact, wash the eyes thoroughly with copious amounts of clean running water.
In case of accidental exposure and a development of symptoms such as skin rash, seek medical advice immediately and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.
Wash hands after use.

Lactation:
Can be used 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:
No information available.

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

7. Adverse events

Cattle (lactating cows):

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Hypersensitivity reaction i.e., allergic skin reaction*, anaphylaxis (severe allergic reaction)*

* 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.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

Intramammary use.

1000 mg oxacillin sodium per affected udder quarter, corresponding to 10 g of the veterinary medicinal 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 periods

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

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25 °C.

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 precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 52644/3000

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

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse events:
Pharmanovo Veterinararzneimittel GmbH
Liebochstrasse 9
Dobl
Dobl-Zwaring
Steiermark
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

<Local representatives and contact details to report suspected adverse events:>

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

Gavin Hall
Approved: 22 July 2026