SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Novocillin LC 1000 mg intramammary suspension for lactating cows

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each intramammary syringe of 10 g contains:

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

Excipients:

Qualitative composition of excipients and other constituents
Paraffin, white soft
Triglycerides, medium-chain

White to almost white suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (lactating cows)

3.2 Indications for use for each target species

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

3.3 Contraindications

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

3.4 Special warnings

None.

3.5 Special precautions for use

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle (lactating cows):

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

* 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Lactation:
Can be used during lactation.

3.8 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).

3.9 Administration routes and dosage

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 veterinary medicinal product before use.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No information available.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QJ51CF04

4.2 Pharmacodynamics

Oxacillin is a semi-synthetic β-lactam antibiotic, resistant to penicillinase. Like other penicillins it has a bactericidal effect on proliferating bacteria by inhibition of cell wall synthesis. Oxacillin shows activity against numerous streptococci and staphylococci, also including β-lactamase-forming bacteria. However, other than in β-lactamase-producing staphylococci, the activity is considerably lower than that of benzylpenicillin. Oxacillin shows good *in vitro* activity against *Streptococcus agalactiae* which is a significant mastitis pathogen. Oxacillin is ineffective against Enterococci and against gram-negative bacteria.

The most relevant mechanism of resistance is the acquisition of a gene encoding a modified penicillin-binding protein with reduced affinity to the drug.

4.3 Pharmacokinetics

The plasma protein binding of oxacillin is reported at >90%. The elimination takes place via the milk, on one hand, and on the other hand renally following systemic absorption.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

Do not store above 25 °C.

5.4 Nature and composition of immediate packaging

Intramammary syringe, plunger and cap made of LLDPE

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

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Pharmanovo Veterinararzneimittel GmbH

7. MARKETING AUTHORISATION NUMBER

Vm 52644/3000

8. DATE OF FIRST AUTHORISATION

21 October 2021

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

June 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

Gavin Hall
Approved: 22 July 2026