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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Intramammary suspension
White to almost white suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (lactating cows)

4.2 Indications for use, specifying the target species

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

4.3 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.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

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 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.

4.6 Adverse reactions (frequency and seriousness)

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).

4.7 Use during pregnancy, lactation or lay

The product is intended for use during lactation.

4.8 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).

4.9 Amounts to be administered and administration route

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No information available.

4.11 Withdrawal period(s)

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

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for intramammary use, beta-lactam resistant penicillins
ATC vet code: QJ51CF04 – Oxacillin

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Paraffin, white soft
Triglycerides, medium-chain

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after first opening the immediate packaging: use immediately.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Intramammary syringe, plunger and cap made of LLDPE
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.

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

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 52644/3000

9. DATE OF FIRST AUTHORISATION

21 October 2021

10. DATE OF REVISION OF THE TEXT

April 2022

Approved: 07 April 2022