Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovaclox Milking Cow Intramammary Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 g syringe contains:

Active Substances:

Ampicillin (as Ampicillin Sodium)	75 mg
Cloxacillin (as Cloxacillin Sodium)	200 mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Intramammary suspension. An off-white suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cows.

4.2 Indications for use, specifying the target species

Bovaclox Milking Cow is an intramammary suspension specially formulated for the broad spectrum treatment of clinical mastitis in lactating cows only.

Bovaclox Milking Cow is effective against Gram-positive and Gram-negative bacteria including *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, and other Streptococcal species, penicillin-resistant and penicillin-sensitive Staphylococci, *Corynebacterium pyogenes*, *Escherichia coli*.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Before infusion, the teat should be thoroughly cleaned and disinfected and care should be taken to avoid contamination of the injector nozzle. Following infusion, it is advisable to use a teat dip or spray.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Penicillin 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 reaction to these substances may occasionally be serious.

1. Do not handle this product if you know you are sensitised or if you have been advised not to work
with such preparations.

2. Handle this product with care to avoid exposure.

3. 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 and eyes or difficulty with breathing are more serious symptoms and
require urgent medical attention.

4.6 Adverse reactions (frequency and seriousness)

No known undesirable effects.

4.7 Use during pregnancy, lactation or lay

Bovaclox Milking Cow is specifically indicated for the treatment of clinical mastitis in lactating cows. It can be safely administered to pregnant animals.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

The contents of one syringe should be infused into each affected quarter via the teat canal immediately after milking at 12 hour intervals for three consecutive milkings.

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

Not applicable.

4.11 Withdrawal period(s)

Milk for human consumption must not be taken from a cow during treatment.
Milk for human consumption may only be taken after 72 hours from the last treatment.
Animals must not be slaughtered for human consumption during treatment.
Cattle may be slaughtered for human consumption only after 4 days from the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Combination of antibacterials for intramammary use, Beta-lactam antibacterials
ATCvet Code: QJ51RC

5.1 Pharmacodynamic properties

Ampicillin possesses antibacterial activity against Gram-positive and Gram-negative bacteria. Cloxacillin is active against Penicillin G resistant staphylococci. Both antibiotics bind membrane bound proteins known as penicillin-binding proteins (PBP's).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid Paraffin
White Soft Paraffin

6.2 Major incompatibilities

Not applicable.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

5 g single dose white syringes with low density polyethylene barrel, plunger and end cap supplied in cartons of 24 syringes.

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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/006/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1987
Date of last renewal: 30 September 2007

10 DATE OF REVISION OF THE TEXT

January 2019