Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Ubro Red Dry Cow Intramammary Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml dose unit contains the following active ingredients:

Penethamate Hydriodide	100.0	mg
Procaine Benzylpenicillin	300.0	mg
Framycetin Sulphate	100.0	mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Intramammary suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Bovine

4.2 Indications for use, specifying the target species

For routine use in cows to treat existing intramammary infections at drying off and to assist in preventing new infections occurring during the dry period.

In vitro efficacy has been demonstrated against the following organisms:

Staphylococcus spp.
Streptococcus spp.
Cornynebacteria spp.
Escherichia coli
Klebsiella spp.
Pseudomonas spp.

4.3 Contraindications

Do not administer to animals with known sensitivity to the active ingredients.
Do not use in the lactating cow.
Not intended for use within 28 days of calving.

4.4 Special warnings for each target species

Where there is a risk of summer mastitis, additional management procedures, such as fly control, should be considered.

4.5 Special precautions for use

Special precautions for use in animals

Before infusion, the teats should be thoroughly cleansed 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 sensitivity 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 great care to avoid exposure, taking all recommended precautions.

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)

None known.

4.7 Use during pregnancy, lactation or lay

Product is safe for use in the pregnant cow.Use in lactating cow is contraindicated.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

The contents of one syringe should be infused into each quarter via the teat canal immediately after the final milking of a lactation.

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

Not applicable.

4.11 Withdrawal period(s)

Milk for human consumption may be taken from 84 hours after calving. If calving occurs before 28 days after last treatment, milk for human consumption may only be taken from 28 days plus 84 hours from the last treatment.

Animals may not be slaughtered for human consumption until 28 days from the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Combination of antibacterials for ntramammary use, Beta-lactam antibacterials
ATCvet Code: QJ51RC
The product contains a combination of 3 antibiotics suspended in slow release base especially designed for dry cow therapy.

Following infusion the components are slowly released by the base and retained in the udder over a prolonged period. The penicillin components of Leo Red Dry Cow will remain in the dry udder for up to 3 weeks. In the majority of cows, the framycetin component will remain in the dry udder for 10 to 14 weeks, or until “bagging up” prior to calving.
Procaine penicillin and penethamate hydriodide have a similar range of activity, and micro-organisms sensitive *in vitro* to the combination include streptococci, penicillin-sensitive staphylococci, corynebacteria and anaerobic micrococci.
Micro-organisms sensitive *in vitro* to framycetin include penicillin-resistant staphylococci, *E.coli* and other gram negative bacteria.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium monostearate
Hydroxystearin
Liquid Paraffin

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months

6.4 Special precautions for storage

Do not store above 25ºC.

6.5 Nature and composition of immediate packaging

Plastic injectors (cylinder with piston and cap, all made of polyethylene) containing 5 ml of a sterile, white, intramammary suspension. Supplied in cartons of 20 and 120.

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

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA10454/010/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1987
Date of last renewal: 30th September 2007

10 DATE OF REVISION OF THE TEXT

July 2018