Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Ubro Yellow Milking Cow Intramammary Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml dose unit contains the following active ingredients:

Penethamate hydriodide	150	mg
Dihydrostreptomycin (as the sulphate)	150	mg
Framycetin sulphate	50	mg
Prednisolone	5	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

The treatment of mastitis caused by organisms sensitive to penicillin, streptomycin or framycetin in milking cows.

4.3 Contraindications

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

4.4 Special warnings for each target species

None.

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 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 during pregnancy and lactation.

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 injector to be infused into each infected quarter every 24 hours for 3 days.

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

Not applicable.

4.11 Withdrawal period(s)

Animals intended for human consumption should not be slaughtered until 7 days from the last infusion.Milk for human consumption must not be taken from a cow during treatment. With cows milked twice daily, milk must be discarded for 5 days and can be released for human consumption at the 11thmilking (132 hours) after the last treatment. With other milking routines, the basis of the veterinary surgeon's advice should be that milk may be taken for human consumption only after the same period from the last treatment. For example, with three times a day milking, milk may be released for human consumption at the 16thmilking after the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Combination of antibacterials for intramammary use, antibacterials and corticosteroids
ATCvet Code: QJ51RV01

The product was formulated to meet the requirements of activity against the strains of bacteria known to be involved in mastitis. Prednisolone was incorporated to reduce the inflammatory reaction and hasten the healing of the infected gland.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose Anhydrous
Polyoxyl 35 Castor oil
Coconut Oil, Fractioned

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 25°C.

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, off-white, intramammary suspension. Supplied in cartons of 20.

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)

VPA10454/015/001

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