SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF VETERINARY MEDICINAL PRODUCT

Ubro Yellow Milking Cow Intramammary Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml injector contains the following active ingredients:

Penethamate Hydriodide	150 mg
Dihydrostreptomycin Sulphate (Equivalent to Dihydrostreptomycin 150mg)	185 mg
Framycetin sulphate	50 mg
Prednisolone	5 mg

For a full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Intramammary suspension.
Opaque off-white suspension.

4. CLINICAL PARTICULARS

4.1 Target Species

Bovine

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

None

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

During the course of treatment, the situation should be reviewed frequently by close veterinary supervision.

(i) Special precautions for use in animals

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

(ii) 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 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 or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

4. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known

4.7 Use during pregnancy, lactation or lay

Can be used 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

Infuse one injector every 24 hours for three days into the affected quarter after milking, using strict aseptic precautions. 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.

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

Not applicable

4.11 Withdrawal period(s)

Cattle (meat and offal): 28 days
Cattle (milk): 132 hours

5. PHARMACOLOGICAL PROPERTIES

ATC Vet Code: QJ51RV01

The product contains a combination of antibiotics which give a wide spectrum of *in vitro* antibacterial activity against staphylococci, (including penicillin resistant strains), streptococci, (*Str. agalactiae, Str. dysgalactiae* and *Str. uberis)* corynebacteria*, Arcanobacterium pyogenes, E.coli, Klebsiella* and *Pseudomonas.*

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose Anhydrous
Poloxyl 35 Castor oil
Coconut Oil, Fractioned

6.2 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
The syringe must only be used once. Part used syringes must be discarded

6.5 Nature and composition of immediate packaging

5ml polyethylene, pre-filled intramammary tube with a butyl rubber piston seal.
Boxes of 20 or 24 injectors. 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 products should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd

Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

8. MARKETING AUTHORISATION NUMBER

Vm 08327/4305

9. DATE OF FIRST AUTHORISATION

29 March 1985

10. DATE OF REVISION OF TEXT

November 2018

Approved: 09 November 2018