SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF VETERINARY MEDICINAL PRODUCT

Ubro Red Dry Cow Intramammary Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml injector contains the following active ingredients:

Penethamate Hydriodide	100 mg
Procaine penicillin	300 mg
Framycetin sulphate	100 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

Cattle

4.2 Indications for use, specifying the target species

Routine dry cow therapy is established as an important part of mastitis control, in conjunction with teat dipping and other managemental factors. The product is indicated for the treatment of sub-clinical infections present at drying off. It also assists in preventing new infection occurring during the dry period. In the case of E.coli infections, this results in a reduction in the incidence of clinical mastitis during the first 100 days of the following lactation.

4.3 Contra-indications

Not intended for use within 28 days of calving.
Not to be used in the lactating cow.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

None

i. 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.

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. 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
Not to be used in the lactating cow

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amounts to be administered and administration route

One injector per quarter at drying off. Each quarter should be infused with the contents of one injector immediately after the last milking or lactation. Before infusing the teats should be thoroughly cleaned and disinfected and care should be taken to avoid contamination of the injector nozzle. Following infusion the teats should be dipped or sprayed with a teat disinfectant.

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

Not applicable

4.11 Withdrawal period(s)

Cattle (meat and offal): 28 days

Cattle (milk): Milk for human consumption may only be taken from 84 hours (7 milkings) after calving. If calving occurs before 28 days after the last treatment, milk for human consumption may only be taken after 28 days plus 84 hours after the last treatment.

5. PHARMACOLOGICAL PROPERTIES

ATC Vet Code: QJ51RC23

Pharmacotherapeutic Group: Antibacterials for intramammary use, Combination of antibacterials for intramammary use, Beta-lactam antibacterials, penicillins, combinations with other antibacterials.

The product contains a combination of an aminoglycoside, a penicillin ester and a penicillin salt, which gives a wide spectrum of antibacterial activity suspended in a slow-release base specifically designed for dry cow therapy. Following infusion, framycetin sulphate and the penicillin component are released slowly by the base and retained in the udder over a prolonged period.

Penethamate Hydriodide has a similar range of activity as procaine penicillin and *in-vitro*, micro-organisms sensitive to the procaine penicillin/penethamate hydriodide combination include streptococci, penicillin-sensitive *staphylococci, Arcarnobacterium pyogenes, Corynebacterium bovis and anaerobic micrococci.*

The penicillin component will remain above the M.I.C's of these micro-organisms for up to 3 weeks in most dry udders. Micro-organisms, sensitive in-vitro to framycetin include penicillin resistant staphylococci, E coli and other Gram-negative bacteria.

The framycetin component will remain above the M.I.C.s of these micro-organisms for up to 14 weeks in most dry udders, though the effect of "bagging up" will reduce the concentration of framycetin to insignificant levels from a few days before calving.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrogentated Castor Oil
Aluminium Monostereate
Liquid Paraffin

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 and red HDPE cap or LDPE pre-filled intrammammary tube with a butyl rubber piston seal and orange LDPE cap.

Boxes of 20 injectors. Herd packs of 120 injectors containing medicated teat wipes.

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 Ave
Bracknell
Berkshire
RG12 8YS

8. MARKETING AUTHORISATION NUMBER

Vm 08327/4304

9. DATE OF FIRST AUTHORISATION

29 March 1985

10. DATE OF REVISION OF TEXT

November 2018

Approved: 09 November 2018