SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ORBENIN Dry Cow 500 mg Intramammary Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient	**g/dose**
Cloxacillin benzathine (equivalent to Cloxacillin	0.5)

Other ingredients

Mineral oil base to	3.0

For the full list of all other excipients see section 6.1

3. PHARMACEUTICAL FORM

Intramammary suspension.
White to off-white viscous suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle.

4.2 Indications for use, specifying the target species

For the infusion of cows at drying off, to treat mastitis infections and to provide protection against further infections during the dry period.

4.3 Contraindications

Do not use in the lactating cow.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i) Special precautions for use in animals

For single use only.

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 penicillins may lead to cross reactions to cephalosporins and vice versa. Allergic reaction to these substances may occasionally be serious.
Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.
Handle this product with great care to avoid exposure, taking all recommended precautions.
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 may required urgent medical attention.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

Not for use in lactating cows.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

One syringe per quarter, immediately after the final milking of lactation. At drying off, clean and disinfect the teat following the last milking, insert nozzle into the teat and apply gentle and continuous pressure until the suspension is expressed.
Each syringe must only be used once. Part used syringes must be disposed of, see section 6.6 for disposal advice.

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

Not applicable.

4.11 Withdrawal periods

Not intended for use within 30 days of calving. Milk for human consumption may only be taken from 204 hours after calving. If calving

occurs before 30 days after last treatment, milk for human consumption may only be taken after 30 days plus 204 hours after last treatment.
Animals must not be slaughtered for human consumption during treatment.
Cattle may be slaughtered only after 28 days from the last treatment.

5. PHARMACOLOGICAL PROPERTIES

The product is active against Gram-positive organisms associated with mastitis.
It is effective against *Streptococcus agalactiae* and other Streptococcal species, straphylococci (penicillin resistant and sensitive strains) and *Corynebacterium pyogenes*. Cloxacillin is bactericidal in activity and is resistant to β-lactamases. Formulated in the long-acting aluminium stearate base the Benzathine salt provides continued activity over 3 to 4 weeks.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium Stearate
Liquid Paraffin
Stearic Acid

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 4 years.

6.4 Special precautions for storage

Do not store above 25˚C.

6.5 Nature and composition of immediate packaging

Suspension for intramammary infusion in white low density polyethylene intramammary syringe barrel containing 3 g of product and plunger. The closure is a white low density polyethylene push-fit combined dual nozzle and cap.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
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8. MARKETING AUTHORISATION NUMBER

Vm 42058/4088

9. DATE OF THE FIRST AUTHORISATION

29 March 1985

10. DATE OF REVISION OF THE TEXT

September 2020

Approved 04 September 2020