SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ORBENIN Extra Dry Cow 600 mg Intramammary Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient:
Benzathine Cloxacillin equivalent to cloxacillin 600 mg/syringe.

For a full list of excipients, see Section 6.1

3. PHARMACEUTICAL FORM

Intramammary suspension, dry cow.

4. CLINICAL PARTICULARS

4.1 Target Species

Cows.

4.2 Indications for Use, Specifying the Target Species

Orbenin Extra Dry Cow is recommended for use in cows at drying off, to treat existing intramammary infections and to provide protection against further infections during the dry period. The concomitant use of Orbeseal at drying off provides additional protection against the ingress of udder pathogens, contributing to preventing both subclinical infections and clinical mastitis during early lactation.

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

None.

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 require 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 to be infused per quarter immediately after cleaning and disinfecting the teats following the last milking before drying off. Thoroughly clean and disinfect the teat orifice before use. Care should be taken to avoid contamination of the syringe nozzle. After infusion it is advisable to dip each teat in an authorised teat dip.

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

Not applicable.

4.11 Withdrawal periods

The following applies to the use of Orbenin Extra Dry Cow either alone or in combination with Orbeseal. Not intended for use in cows with dry periods of 42 days or less. Milk for human consumption may only be taken from 96 hours after calving (that is, at the eighth milking in cows milked twice daily). If calving occurs before 42 days after last treatment, milk for human consumption may only be taken from 42 days plus 96 hours after the last treatment. Cattle must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption 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, Streptococcus dysgalactiae, Streptococcus uberis*, penicillin-resistant and penicillin-sensitive staphylococci and *Corynebacterium pyogenes (Actinomyces pyogenes).*

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Stearic Acid
Aluminium Stearate
Liquid Paraffin

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special Precautions for Storage

Do not store above 25°C.
The syringe may only be used once. Part used syringes must be discarded.

6.5 Nature and composition of immediate packaging

Off-white suspension in white low density polyethylene syringes for intramammary infusion.
Cartons containing 24 and 120 (2 x 60) syringes.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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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Springfield Drive
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KT22 7LP

8. MARKETING AUTHORISATION NUMBER

Vm 42058/5211

9. DATE OF THE FIRST AUTHORISATION

09 February 1988

10. DATE OF REVISION OF THE TEXT

May 2025

Gavin Hall
Approved: 20 May 2025