SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Orbenin L.A. 200 mg Intramammary Suspension for Cattle and Sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 3 g dose contains:

Active substance:
Cloxacillin as Cloxacillin sodium 200 mg

Excipients:

Qualitative composition of excipients and other constituents
Hydrogenated Castor Oil
Silica Hydrophobic Colloidal
Butylated Hydroxyanisole
Arachis Oil

Off-white, stable suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle and sheep.

3.2 Indications for use for each target species

The veterinary medicinal product is indicated for intramammary use in the treatment of bovine mastitis caused by Gram-positive organisms. For the best results it should be used at the earliest signs of infection.

The product is also indicated as an intramammary infusion in ewes at weaning for the treatment and prevention of mastitis. The veterinary medicinal product is effective against *Streptococcus agalactiae* and other streptococcal species, penicillin-resistant and sensitive staphylococci and *Actinomyces pyogenes.*

In staphylococcal and certain forms of streptococcal mastitis, an adequate duration of treatment is important in achieving both clinical and bacteriological cures. The veterinary medicinal product with its slow release characteristics is designed to meet these requirements.

3.3 Contraindications

None.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Individual syringes must only be used once.

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.

People with known hypersensitivity should avoid contact with the veterinary medicinal product.

Handle this product with great care to avoid exposure, taking all recommended precautions.

In case of accidental self-administration, seek medical advice immediately and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Wash hands after use.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Lactation:
The veterinary medicinal product is indicated for use in the lactating cow and for use in ewes at weaning.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Cows
Dosage
The recommended dose is three infusions per infected quarter - one syringe administered every 48 hours.
Administration
Clean and disinfect the teat with surgical spirit after milking; insert nozzle into the teat and apply gentle and continuous pressure until the suspension is expressed. The treated quarter(s) may be milked out at the next normal milking time.

Ewes
Dosage
A single infusion should be made into each udder half at weaning.
Administration
It is important that a simple hygienic procedure is followed. One operator should turn up and hold each ewe whilst a second person carries out the infusion technique. Clean and disinfect each teat end thoroughly with surgical spirit. Appose the syringe nozzle to the teat orifice and apply gentle, continuous pressure to express the suspension in the udder. Actual cannulation of the teat orifice is neither necessary nor desirable. Use a fresh syringe for each udder half to avoid the possibility of cross contamination during infusion.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

The veterinary medicinal product is non-irritant to the udder tissues and well tolerated in the target species. No adverse effects are to be expected from an accidental overdose.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Cattle (milk): 96 hours.
Sheep (milk): Not for use in ewes producing milk for human consumption.
Cattle and sheep (meat and offal): 7 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ51CF02

Cloxacillin, a semi-synthetic β-lactam antibiotic, is active against Gram-positive organisms, but is not destroyed by staphylococcal penicillinase. It is therefore active against penicillin resistant staphylococci which are an important cause of mastitis.
The antibiotic is bactericidal at the concentrations produced in the udder and is non-irritant to the udder tissues.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

Do not store above 25 °C.
Store in a dry place.

5.4 Nature and composition of immediate packaging

Polythene syringes in packs of 12 syringes per carton.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited

7. MARKETING AUTHORISATION NUMBER

Vm 42058/5165

8. DATE OF FIRST AUTHORISATION

14 January 1995

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

June 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 31 July 2025