SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Orbenin L.A. 200 mg Intramammary Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 3 g dose unit contains the following:

Active ingredient
Cloxacillin as cloxacillin sodium 200 mg

Other ingredients
Vegetable oil base to 3 g

For the full list of all other excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Intramammary suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle and sheep.

4.2 Indications for use, specifying the target species

Orbenin L.A. 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. Orbenin 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. Orbenin L.A. with its slow release characteristics is designed to meet these requirements.

4.3 Contraindications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i) Special precautions for use in animals

Individual syringes must only be used once.

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 require urgent medical attention.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

Orbenin L.A. is indicated for use in the lactating cow and for use in ewes at weaning.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Cows
Dosage
The recommended dose is three infusions per infected quarter - one syringe administered every 48 hours.

Dosing guide
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.

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

Orbenin L.A. 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.

4.11 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

5. PHARMACOLOGICAL PROPERTIES

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.

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6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrogenated Castor Oil
Silica Hydrophobic Colloidal
Butylated Hydroxyanisole
Arachis Oil

6.2 Incompatibilities

None.

6.3 Shelf-life

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

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Polythene syringes in packs of 12 syringes per carton.

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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KT22 7LP

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4090

9. DATE OF THE FIRST AUTHORISATION

14 January 1995

10. DATE OF REVISION OF THE TEXT

September 2020

Approved 04 September 2020