

IRISH MEDICINES BOARD ACT 1995

ANIMAL REMEDIES REGULATIONS, 2005

(S.I. No. 734 of 2005)

VPA: **10019/030/001**

Case No: 7002035

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies Regulations (S.I. No. 734 of 2005) hereby grants to:

Pfizer Healthcare Ireland

Trading as Pfizer Animal Health, Ringaskiddy, Co. Cork, Ireland

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Orbenin LA

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

ORBENIN L.A.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 3 g dose unit contains the following:

Active Substance

Cloxacillin (as cloxacillin sodium)	200 mg
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Excipients

Vegetable oil base to	3 g
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For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Intramammary suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle

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.

In vitro, 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

Do not use in animals with known sensitivity to the active ingredient.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precaution(s) for use

Individual syringes must only be used once.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Operator warning:

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.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Orbenin L.A. is indicated for use 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

Dosage

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

Dosing guide

Clean and disinfect teat with surgical spirit after milking, insert nozzle into the teat and apply gentle and continuous pressure until the suspension is expressed. Care should be taken to avoid contamination of the injector nozzle. The treated quarter(s) may be milked out at the next normal milking time. Following infusion, it is advisable to use a teat dip or spray.

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

Orbenin L.A. is non-irritant to the udder tissues and is well tolerated in the target species. No adverse effects are to be expected from an accidental overdose.

4.11 Withdrawal Period(s)

Milk for human consumption must not be taken from a cow during treatment. With cows milked twice daily, milk for human consumption may only be taken from 84 hours (ie. at the 7th milking) after the last treatment.

With other milking routines, the basis of the veterinary surgeon's advice should be that milk may be taken for human consumption only after the same period from the last treatment (for example, with three times a day milking with the product administered every 48 hours, milk for human consumption may only be taken at the 11th milking).

Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 7 days from the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Orbenin 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Vegetable oil base

The vegetable oil base has the following composition:

Hydrogenated castor oil
Colloidal silica (Aerosil R972)
Butylated hydroxyanisole
Arachis Oil

6.2 Incompatibilities

None known.

6.3 Shelf-life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

Polythene syringes containing a sterile off-white hydrophobic suspension for single use only. Packs of 12 syringes per carton.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Pfizer Healthcare Ireland
Trading as Pfizer Animal Health
Ringaskiddy
County Cork
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10019/30/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2002