

IRISH MEDICINES BOARD ACT 1995

MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998

(S.I. No.142 of 1998)

10995/010/001

Case No: 7002385

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Ceva Animal Health Limited

90 The Broadway, Chesham, Bucks HP15 1EG, United Kingdom

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Erythrocin Intramammary Solution 300mg

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **15/12/2006** until .

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Erythrocin Intramammary Solution 300mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 6ml syringe contains :

Active substance

Erythromycin	300 mg
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Excipients

Butylated hydroxyanisole	0.4 mg
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Butylated hydroxytoluene	0.4 mg
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Fractionated coconut oil	q.s.	to	6 ml
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For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Intramammary solution

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle

4.2 Indications for use, specifying the target species

For the treatment of clinical and subclinical mastitis in cattle due to erythromycin-sensitive:

Staphylococcus aureus

Streptococcus agalactia

S. dysgalactia

S. uberis

4.3 Contraindications

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

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

None.

4.6 Adverse reactions (frequency and seriousness)

None reported.

4.7 Use during pregnancy, lactation or lay

This product may be used in pregnant and lactating animals

4.8 Interaction with other medicinal products and other forms of interaction

None reported.

4.9 Amounts to be administered and administration route

For intramammary administration.

Thoroughly milk out each infected quarter. Clean the udder and teats by washing carefully and disinfect the teat orifice (s). Infuse the entire contents of one syringe into each infected quarter. Close the teat orifice with gentle pressure and massage the udder to distribute the medication. Repeat after each milking (12-hourly intervals) for a total of three consecutive infusions.

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

No information available but overdosage is most unlikely to occur.

4.11 Withdrawal Period(s)

Milk:

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 36 hours (i.e. at the 3rd milking) from the last treatment.

Tissues:

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

5.1 Pharmacodynamic properties

Erythromycin is a macrolide antibiotic with a bacteriostatic action against a wide range of bacteria, although it also has a bactericidal action against certain pathogenic micro-organisms.

The antibiotic is highly active against gram-positive bacteria and at low concentrations it inhibits many other types of micro-organisms. In addition to the gram-positive bacteria, most strains of *Neisseria* and *Haemophilus* are sensitive as are some strains of *Bordetella*, *Brucella*, *Pasteurella*, *Listeria*, *Actinomyces*, *Mycoplasma*, *Rickettsia*, certain large viruses and *Treponema pallidum*.

In in-vitro studies, the action of erythromycin against gram-positive bacteria, as measured by the minimum inhibitory concentrations, appears to be comparable to that of penicillin.

The mode of action of erythromycin and other macrolide antibiotics is the inhibition of protein synthesis by binding to 50 S ribosomal subunits of sensitive micro-organisms.

Certain resistant micro-organisms with mutational changes in components of this subunit of the ribosome fail to bind the drug.

5.2 Pharmacokinetic properties

When erythromycin is absorbed in the rat, it is excreted in the bile. Also, in rats and dogs erythromycin is converted to des-N-methyl erythromycin and carbon dioxide.

In the rabbit, erythromycin is rapidly demethylated by a microsomal enzyme in the liver to yield des-N-methyl erythromycin and formaldehyde. The latter was derived from the N-methyl group of D-desosamine. With the exception of the adrenal gland, other tissues tested did not cause demethylation of the antibiotic.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylated Hydroxyanisole
Butylated Hydroxytoluene
Fractionated Coconut Oil

6.2 Incompatibilities

None known.

6.3 Shelf-life

15 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

6 ml single-dose polyethylene syringe containing a sterile, viscous light tan solution available in cartons of 24.

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

Ceva Animal Health,
90 The Broadway,
Chesham,
Bucks, HP5 1EG,
United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10995/10/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2003