IRISH MEDICINES BOARD ACT 1995

ANIMAL REMEDIES REGULATIONS, 2005

(S.I. No. 734 of 2005)

VPA: **10987/061/001**
Case No: 7002632

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:

Chanelle Pharmaceuticals Manufacturing Limited

Loughrea, **Co. Galway**, **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:

Chanamast LC Intramammary Suspension

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

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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

Chanamast LC Intramammary Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 4.5g dose contains:

Active substances

Ampicillin (as Ampicillin Sodium)	75	mg
Cloxacillin (as Cloxacillin Sodium)	200	mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Intramammary suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Lactating Cows

4.2 Indications for use, specifying the target species

For the treatment of clinical mastitis in lactating cows caused by:

Streptococcus agalactiae
Streptococcus dysgalactiae
other streptococcal species
Staphylococci (penicillin resistant and sensitive strains)
Corynebacterium pyogenes
Echerichia coli

4.3 Contraindications

Not to be used in animals known to be hypersensitive to the active ingredients

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

None.

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 celphalosporins and vice versa. Allergic reactions 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 care to avoid exposure, taking all the 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.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Chanamast LC is indicated 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

For intramammary administration only.
The contents of one syringe should be infused into each affected quarter via the teat canal, immediately after milking at 12 hour intervals for three consecutive milkings. Before infusion, the teat should be thoroughly cleaned and disinfected and care should be taken to avoid contamination of the injector nozzle. Following infusion, it is advisable to use a teat dip or spray.

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

Not applicable.

4.11 Withdrawal Period(s)

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

Milk for human consumption may only be taken after 72 hours from the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Chanamast LC contains Ampicillin Sodium and Cloxacillin Sodium. The synergism between these two semi-synthetic penicillins has been shown to be due to the inhibition by cloxacillin of the penicillinases produced by various bacteria and subsequent reduction of the extent of inactivation of ampicillin. This combination, therefore, provides a broad spectrum of activity effective against many gram negative and gram positive organisms, including penicillinase producing staphylococci.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Oily base

The oily base consists of:

Liquid Paraffin
Yellow Soft Paraffin
Sorbitan Mono-oleate

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life: 3 years.
The syringe is intended for single use only.

6.4 Special precautions for storage

Do not store above 25^0C.

6.5 Nature and composition of immediate packaging

4.5 g single dose polyethylene syringe containing an off-white, sterile suspension for intramammary administration.

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

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway,
Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10987/61/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24th September 2004