IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10823/011/001**
Case No: 7006773

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Chem-Pharm

Ballyvaughan, **Co. Clare**, **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:

Interclox DC 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.

The authorisation, unless previously revoked, shall continue in force from **30/09/2009**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, 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

Interclox DC Intramammary Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 4.5 g syringe contains:

Active substance:

Cloxacillin (as Cloxacillin Benzathine)	500 mg
Ampicillin (as Ampicillin Trihydrate)	250 mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Intramammary suspension.
An off-white suspension

4 CLINICAL PARTICULARS

4.1 Target Species

Dairy cattle

4.2 Indications for use, specifying the target species

For routine use in the dairy cow at the point of drying off, that is immediately after the last milking of the lactation in order to treat existing mastitis and to provide protection against further infections during the dry period. It also aids in reducing the incidence of summer mastitis in dry cows at risk. The product is active against:

Streptococcus spp
Staphylococcus spp.
Corynebacterium spp.

4.3 Contraindications

Not to be used in lactating cows.
Do not use within 45 days of calving.
Do not use in cows known to be hypersensitive to the active ingredients.

4.4 Special warnings for each target species

In the event of accidental treatment of lactating cows, the milk should be discarded for 30 days following which time the milk should be tested until antibiotics can no longer be detected.

4.5 Special precautions for use

Special precautions for use in animals
When infusing cows it is important that the syringe nozzle is not introduced into the teat. The animal should be properly restrained. The teats are cleaned and disinfected. The teat orifice is located and the nozzle of the syringe placed against it but not inserted. When the syringe plunger is depressed the antibiotic passes easily through the teat orifice into the udder.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Penicillin and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillin may lead to cross sensitivity to cephalosporins and vice versa. Allergic reaction to these substances may occasionally be serious.

1. Do not handle this product if you know you are sensitised or if you have been advised not to work with such preparations.

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

3. 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 and eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

4.6 Adverse reactions (frequency and seriousness)

No known undesirable effects.

4.7 Use during pregnancy, lactation or lay

This product must not be used in the treatment of lactating cows. In freshly calved cows which develop hypocalcaemia, milk should be tested for freedom from antibiotics before being used for human consumption.
The product can be safely administered to pregnant animals.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Dry-off Therapy: After the final milking of a lactation, clean and disinfect the teats and introduce the contents of one tube into each quarter via the teat canal.

Summer Mastitis Therapy: Prior to the first calving, whilst at risk to summer mastitis, clean and disinfect the teats and introduce the contents of one syringe into each quarter at 3 week intervals. During the summer mastitis period, all dry cows should receive a repeated infusion of one syringe into each quarter at 3 week intervals throughout their dry period in addition to the routine drying off therapy.

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

Not applicable.

4.11 Withdrawal Period(s)

Milk for human consumption may only be taken after 120 hours after calving. Do not use in cows with a short dry period. Not intended for use within 45 days of calving. Should a cow calve earlier than 45 days after the last treatment, milk for human consumption may only be taken from 45 days plus 120 hours after the last treatment.
Animals must not be slaughtered for human consumption during treatment.
Cattle may be slaughtered for human consumption only after 28 days from the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Combination of antibacterials for intramammary use, Beta-lactam antibacterials
ATCvet Code: QJ51RC

5.1 Pharmacodynamic properties

Cloxacillin is active against Penicillin G resistant staphylococci. Ampicillin possesses antibacterial activity against Gram-positive and Gram-negative bacteria. Both antibiotics bind to membrane bound proteins known as penicillin-binding proteins (PBP's).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium Stearate
Liquid Paraffin.

6.2 Incompatibilities

Not applicable

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years

6.4 Special precautions for storage

Do not store above 25^{o}C.

6.5 Nature and composition of immediate packaging

4.5 g single dose white polyethylene, self-venting click-lock syringes.
Supplied in cartons of 80 syringes.

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

Chem-Pharm Ltd.
Ballyvaughan
Co. Clare

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10823/011/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2009

10 DATE OF REVISION OF THE TEXT