IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10960/001/001**
Case No: 7007323

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:

Cross Vetpharm Group Ltd.

Broomhill Road, **Dublin 24**, **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:

Osmonds Five in One Intramammary Suspension, --Unknown--

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 revoked, shall continue in force from **19/01/2010**.

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

Osmonds Five in One Intramammary Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 4.5 g contains:	
Active Substances	
Neomycin (as Neomycin Sulphate)	250 mg
Procaine Benzylpenicillin	100 mg
Oxytetracycline Hydrochloride	50 mg
Prednisolone	10 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Intramammary suspension.
A smooth, pale yellow oily suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Lactating Cow.

4.2 Indications for use, specifying the target species

For the treatment of mastitis in lactating cows where broad spectrum cover with an anti-inflammatory dimension is required. *In-vitro* efficacy has been shown against the following organisms:

Streptococcus agalactiae
Streptococcus dysgalactiae,
Streptococcus uberis
Non-specific *Streptococci*
Staphylococcus aureus
Actinomyces pyogenes
Escherichia coli.

4.3 Contraindications

Do not use in animals with known hypersensitivity 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

Before infusion the teat should be thoroughly cleansed and disinfected.

Care should be taken to avoid contamination of the syringe nozzle after the cap has been removed.

Special Precautions to be taken by the Person Administering the Medicinal Product to Animals

Operators should avoid contact with this preparation as occasionally skin allergy may occur.
Penicillins and cephalosporins may cause sensitisation following injection, inhalation, ingestion or skin contact. Sensitivity to penicillins may lead to cross sensitivity to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.
Do not handle this product if you know that you are sensitised or if you have been advised not to work with such preparations.
If you develop symptoms such as a skin rash following exposure, seek medical advise and show this warning to the doctor. 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

This product can be used in pregnant animals.
This product is formulated for infusion into the udder of lactating cows for the treatment of mastitis, and milk for human consumption should be withheld in accordance with the stated withdrawal times.

4.8 Interaction with other medicinal products and other forms of interaction

There is very little systemic absorption from the udder and the potential for interaction is thus very low.

4.9 Amounts to be administered and administration route

For intramammary infusion.

The contents of one injector 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 cleansed and disinfected and care should be taken to avoid contamination of the syringe nozzle.
Following infusion it is advisable to use a teat dip or spray.

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

Care should be taken not to overdose.
Overdosing may invalidate the stated milk and meat withholding times.

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 after 96 hours (i.e. at the 9th milking) from the last treatment.
Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered only after 7 days from the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Combination of antibacterials for intramammary use, antibacterials and corticosteroids
ATCvet Code: QJ51RV01

5.1 Pharmacodynamic properties

Osmonds Five in One is an intramammary product intended for administration to lactating cows. The product is indicated in the treatment of mastitis where broad spectrum cover with an anti-inflammatory dimension is required. The combination of three antibiotics is intended to provide a wide spectrum of antimicrobial activity while prednisolone is included to provide anti-inflammatory activity.

In-vitro efficacy has been shown against *S. agalactiae*, *S. dysgalactiae*, *S. uberis*, non-specific Streptococci, *Staphylococus aureus*, *Actinomyces pyogenes* and *E. coli*. This MIC data was generated using local mastitis isolates and is therefore relevant to the condition for which the product is to be used. This MIC study also provides justification for the inclusion of all three antibiotics.

An indication of udder levels of antibiotics is provided by the milk residue data where it was found that the following levels are exceeded in the milk at 24 hours or more post last infusion.

Antibiotic	Concentration	Hours, post infusion present at this level
Penicillin	>0.048 iu/ml	32
Oxytetracycline	>1.14 mcg/ml	24
Neomycin	> 2.4 mcg/ml	48

The maintenance of these levels between the 3rd and 5th milkings post the final infusion is a positive indication of the persistence of the actives in the udder.
The anti-inflammatory effect of prednisolone was investigated in a series of irritancy studies in which somatic cell counts (SCC) in the milk and clinical symptoms were monitored. The results suggest that the inclusion of prednisolone has beneficial effects in reducing the SCC and prevention of increased inflammation associated with the use of an intramammary product.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polysorbate 80
Liquid Paraffin
Yellow Soft Paraffin
Sorbitan Oleate

6.2 Incompatibilities

None known.

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°C.

6.5 Nature and composition of immediate packaging

Plastic (low density polyethylene) single dose intramammary syringe.

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

Cross Vetpharm Group Limited
Broomhill Road
Tallaght
Dublin 24

Trading as “Osmonds”

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10960/001/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2007

10 DATE OF REVISION OF THE TEXT