IRISH MEDICINES BOARD ACT 1995

ANIMAL REMEDIES REGULATIONS, 2005

(S.I. No. 734 of 2005)

VPA: **10835/045/001**
Case No: 7001560

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:

Novartis Animal Health

Industrial Park, **Cork Road**, **Waterford**

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:

Vetimast 235mg 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 this

_____

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

Vetimast 235mg Intramammary Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each intramammary syringe contains cefacetrile (as cefacetrile sodium) 235 mg. Each syringe contains 10 g intramammary suspension.

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Intramammary suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Lactating Bovine.

4.2 Indications for use, specifying the target species

Treatment of mastitis

Target species:

Streptococcus agalactia
S. dysagalactia
S. uberis
Staphlococcus aureus (both penicillin sensitive and resistant strains)
E. coli
Klebsiella

4.3 Contraindications

None.

4.4 Special warnings for each target species

Cafacetrile is not active against Pseudomonas, moulds or yeast.

4.5 Special precautions for use

Special precautions for use in animals

Before infusion, the teats should be thoroughly cleaned and disinfected and care should be taken to avoid contamination of the injector nozzle.

Special Precautions to be taken by the Person Administering the 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 can 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 and 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 is used during lactation and pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Intramammary infusion of the contents of one syringe per affected quarter. Before infusion, the teats 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)

Milk: 72 hours (6 milkings)
Milk should not be taken until after the 6^{th} milking.

Meat: There is a zero withholding period for affected cows following infusion.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Antibiotic

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Stearic Acid
Microcrystalline
Peanut Oil

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf Life : 3 years
Each 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

A single dose plastic (HDPE) syringe containing 10 g of an off-white sterile hydrophobic suspension. 4 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

Novartis Animal Health Ireland
Industrial Park
Waterford
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10835/45/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01 October 2002