IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10960/021/001**
Case No: 7004806

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:

Bimastat Oral 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 **30/09/2008**.

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

Bimastat Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance		
Sulfadiazine	150.0	mg/ml
Neomycin (as neomycin sulphate)	25.0	mg/ml
Excipients		
Methyl parahydroxybenzoate	2.0	mg/ml
Propyl parahydroxybenzoate	0.2	mg/ml
Carmoisine E122	0.05	mg/ml

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension

4 CLINICAL PARTICULARS

4.1 Target Species

Pre-ruminant calves.

4.2 Indications for use, specifying the target species

For the treatment of diarrhoea in pre-ruminant calves associated with infections caused by organisms known to be, or suspected of being, susceptible to the combination of sulfadiazine and neomycin.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredients.
Do not exceed the recommended dosage or the period of treatment.
Do not use local anaesthetics of the procaine group during treatment as they are antagonistic to the sulphonamide component.
Do not use in calves with functional rumens.
Do not use in lactating cows.
Do not use in foals and horses.

4.4 Special warnings for each target species

Concurrent intravenous fluid therapy should be considered in dehydrated calves. Parenteral antibiotic treatment should be considered if a clinical response is not seen after 48 hours treatment.

4.5 Special precautions for use

Special precaution(s) for use in animals

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Avoid contact with skin.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Chronic usage of oral neomycin may result in bacterial or fungal superinfections.

4.7 Use during pregnancy, lactation or lay

The product is intended for use in calves only. Do not use in lactating cows.

4.8 Interaction with other medicinal products and other forms of interaction

There is interaction and antagonism between sulphonamides and the Vitamin B Complex. Do not use local anaesthetics of the procaine group during treatment, as they are antagonistic to the sulphonamide component.

4.9 Amounts to be administered and administration route

Administration is by oral drench.

Shake well before use.

The recommended dose is:

4 ml per 10 kg bodyweight twice daily. This equates to 60 mg/kg Sulphadiazine, 10 mg/kg Neomycin and 42 mg/kg Kaolin twice daily.

The maximum period of treatment is 5 days.

To ensure a correct dosage, bodyweight should be determined as accurately as possible.

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

Good tolerance has been confirmed in calves at x3 and x5 the recommended dose rate.

4.11 Withdrawal Period(s)

Animals intended for human consumption must not be slaughtered during treatment. Calves intended for human consumption may only be slaughtered after 28 days from the last treatment. Not intended for animals producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Sulfonamides, combinations with other antibacterials

ATCvet code: QJ01RA02

5.1 Pharmacodynamic properties

Sulphadiazine is a broad spectrum antimicrobial agent. It acts by interfering with the biosynthesis of folic acid in bacterial cells, competitively preventing para-aminobenzoic acid (PABA) from incorporation into the folic acid molecule. It is rapidly absorbed from the gastrointestinal tract and widely distributed to all tissues and body fluids. The sulphonamides are eliminated by a combination of renal excretion and biotransformation.

Neomycin is the isomeric mixture of Neomycin B and C. It has a rapid dose related bactericidal action on susceptible microorganisms. The antibacterial action is directed primarily against aerobic gram negative bacteria. It is poorly absorbed from the gastrointestinal tract, has a short life and is nearly all excreted unchanged in the faeces. Kaolin is a standard long established adsorbent in human and veterinary medicine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric Acid anhydrous
Light Kaolin
Methyl Parahydroxybenzoate
Propyl Parahydroxybenzoate
Sodium Citrate
Xanthan Gum
Povidone 90
Propylene Glycol
Polysorbate 20
Simethicone emulsion
Carmoisine (E122)
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 18 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

250 ml, 400 ml and 1 litre white high density polythylene bottles, sealed with a tamper-evident cap containing a pink oral suspension.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused product or waste materials should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Cross Vetpharm Group Ltd.,
Broomhill Road,
Tallaght,
Dublin 24.

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10960/021/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2008

10 DATE OF REVISION OF THE TEXT