IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10988/059/001**
Case No: 7007551

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:

Virbac S.A.

Virbac 1, 1 ere Avenue, **2065 M - L.I.D., BP 27, 06516**, **Carros Cedex**, **France**

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:

Enterogram Oral Paste

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 **31/03/2010** until **14/10/2009**.

Signed on behalf of the Irish Medicines Board

_____

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

Enterogram Oral Paste

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance		
Colistin (as sulfate form)	2.25 Million I.U.	
Excipients		
Methylparahydroxybenzoate		6 mg
Excipient	qs	5 ml

3 PHARMACEUTICAL FORM

Oral paste.

4 CLINICAL PARTICULARS

4.1 Target Species

Calves.

4.2 Indications for use, specifying the target species

For the treatment and control of gastrointestinal infections caused by organisms sensitive to colistin in calves: *E. coli, Salmonella*.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.

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

None.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Administration is by the oral route.

The recommended dosage is 75,000 iu colistin sulphate per kg bodyweight twice daily for 3 days. This is equivalent to 5ml Enterogram per 30 kg liveweight twice daily. A 12 hourly interval should be observed between treatments.

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

None known.

4.11 Withdrawal Period(s)

Edible tissues from slaughtered animal: 14 days.

Milk: Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Colistin is an antibiotic.

5.1 Pharmacodynamic properties

5.2 Pharmacokinetic properties

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

6.2 Incompatibilities

None.

6.3 Shelf-life

18 months.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and composition of immediate packaging

60 ml syringe of high density white opaque polyethylene with a dose control ring and graduations every 5 ml on the piston.

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

Virbac SA
1ere Avenue - 2065 m LID
06516 Carros
France

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10988/059/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

15th October 2004