IRISH MEDICINES BOARD ACT 1995

ANIMAL REMEDIES REGULATIONS, 2005

(S.I. No. 734 of 2005)

VPA: **10835/001/001**
Case No: 7001568

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:

Collovet Oral solution

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

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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

Collovet Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The product contains:

Active Substances	
Caffeine citrate	1.2000 %w/v
Iron (as green ferric ammonium citrate, iron and manganese citrate)	0.4200 %w/v
Thiamine Hydrochloride	0.0188 %w/v
In a formulation also containing	
Manganese	0.0420 %w/v
Sodium	0.3770 %w/v
Potassium	0.4000 %w/v
Chromium	0.0010 %w/v
Copper	0.0060 %w/v

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Horses, Cattle, Pig, Dog, Cat, Mink, Caged Birds and Poultry.

4.2 Indications for use, specifying the target species

For use as a general tonic.

4.3 Contraindications

Not to be administered to healthy animals receiving an adequate intake of minerals in the diet.

4.4 Special warnings for each target species

In the majority of cases, urinary excretion of caffeine and its metabolites in the horse is virtually complete by 3 days. However, traces of caffeine metabolites have been detected in the urine for up to 10 days after administration. In animals which are to be raced, that is, horses and dogs, for specific information on the time that must elapse between treatment and competition, veterinary surgeons are advised to consult the authority responsible for the competition in question.

4.5 Special precautions for use

Special precautions for use

None known.

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

If ingested by a child, medical attention should be sought immediately taking the product with you.

To the doctor: it is suggested that, for ingestion in humans, emesis be induced and consideration given to the use of oral activated charcoal.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Use with caution in pregnancy, balancing the likely benefits of the recommended dose against the possible risks.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For oral administration only, mixed with milk, water or feed.

Horse: 250 kg - 40 ml two or three times daily
500 kg - 80 ml two or three times daily
750 kg - 120 ml two or three times daily

Foal: 10- 20 ml twice daily in milk.

Cattle: 250 kg - 40 ml two or three times daily
500 kg - 80 ml two or three times daily
750 kg - 120 ml two or three times daily

Calves: 10 - 20 ml twice daily in milk

Pig: Adult - 40 ml twice daily
100 kg - 20 ml twice daily
20 kg - 5 ml twice daily

Dog: 10 kg - 2.5 ml three times daily

Cat: 1 ml three times daily

Mink: 2-3 drops per day in the food, or in water or milk.

Cage birds: 1-2 drops in the drinking water every other day.

Poultry: Dilute with an equal part of water and allow 25 ml Collovet per 9 litres of drinking water (500 ml/40

gallons).

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

There is no specific recommendation : treat symptomatically.

4.11 Withdrawal Period(s)

Edible tissues from slaughtered animals: 28 days

Milk : 7 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Micronutrient supplement.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Copper chloride
Chromium chloride
Sodium glycerophosphate solution
Potassium glycerophosphate solution
Yeatex “M”
Caramel colour (16134 Brown)
Sodium Dihydrogen Orthophosphate
Sodium Benzoate
Nipastat
Ethanol (90 per cent)
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf life: 12 months.

6.4 Special precautions for storage

Do not store above 25^0C.

6.5 Nature and composition of immediate packaging

2 litre amber glass dispensing bottle.

500 ml amber glass winchester.

Contents: Dark brown liquid with odour and taste of beef extract.

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 Ltd.
Industrial Park
Cork Road
Waterford
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10835/1/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2004