

IRISH MEDICINES BOARD ACT 1995

ANIMAL REMEDIES REGULATIONS, 2005

(S.I. No. 734 of 2005)

VPA: **10799/007/001**
Case No: 7002834

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:

Dechra Ltd

Dechra House, Jamage Industrial Estate, Stoke-on-Trent ST7 1XW, United Kingdom

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:

Dalophylline 140 mg/Dose Oral Gel

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

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

Dalophylline 140 mg Oral Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Active Substance</u>	<u>per unit dose</u>	
Etamiphylline Camsylate	140	mg
<u>Excipients</u>		
Sodium Methylparahydroxybenzoate	3	mg
Sodium Propylparahydroxybenzoate	1	mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

A colourless, transparent oral gel.

4 CLINICAL PARTICULARS

4.1 Target Species

Calves and lambs.

4.2 Indications for use, specifying the target species

Etamiphylline Camsylate is a smooth muscle relaxant and cardiac and respiratory stimulant. It is indicated in the treatment of cardiac and respiratory failure and distress and it may be of use in pneumonia and upper respiratory tract infections. Dalophylline gel is indicated in the treatment of neonatal weakness in lambs and calves, associated with cardiac and respiratory distress particularly following dystocia or caesarean section.

4.3 Contraindications

None.

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

Wash hands after use.

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

Lambs: for neonatal weakness: 1 unit dose. A second unit dose may be given 3-4 hours later if required. Larger lambs (over 2.5kg) may require 2 unit doses.

Calves: For neonatal weakness: 5 unit doses. A further 5 units may be given 3-4 hours later if required.

Each unit dose (one complete turn of the ring) is equivalent to 140mg Etamiphylline Camsylate. Turn the ring to the required dose, remove the cap and express the dose as near to the back of the tongue as possible. Replace the cap after use. Each marked division is equivalent to 2 unit doses.

For oral administration.

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

Overdose is always a risk. Signs of toxicity include restlessness, increased heart and respiratory rates and convulsions in severe cases. Treatment is symptomatic.

4.11 Withdrawal Period(s)

Cattle - Meat: 7 days.

Sheep - Meat: 7 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: respiratory stimulant

ATC Vetcode: QR03DA06

5.1 Pharmacodynamic properties

Etamiphylline Camsylate is a water soluble compound claimed to have similar therapeutic effects to Theophylline but with much improved solubility and reduced tissue irritancy and toxicity. It is a smooth muscle relaxant, and cardiac and respiratory stimulant. In common with other methyl xanthines, etamiphylline is thought to inhibit the phosphodiesterase responsible for hydrolysis of cyclic AMP leading to increases of this intracellular messenger. It has also been shown to have an antagonistic effect on the action of adenosine within the central nervous system, thus causing stimulation of the neurones. The drug is used as a cardiac and respiratory stimulant in the treatment of neonatal weakness in calves and lambs.

5.2 Pharmacokinetic properties

In calves only oral administration is effective. The plasma half-life is short, about 100 minutes in the horse and about 60 minutes in the dog and in calves.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene Glycol
Hydroxyethylcellulose
Hexaflavour Vanilla
Saccharin Sodium
Sodium methylhydroxybenzoate
Sodium propylhydroxybenzoate
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf-life

3 years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

A high density polyethylene dial-a-dose syringe with barrel, plunger, cap and dosage selector ring. Each syringe contains 10 unit doses.

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

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

7 MARKETING AUTHORISATION HOLDER

Dechra Limited,
Dechra House,
Jamage Industrial Estate,
Talke Pits,
Stoke-on-Trent,
ST7 1XW,
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

Ireland: VPA 10799/007/001
UK: Vm 01732/4115

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2005

10 DATE OF REVISION OF THE TEXT

8th November 2006

8th December 2006

19th January 2007