IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10799/010/001**
Case No: 7004723

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:

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:

Millophylline-V 100 mg Oral Tablets

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 **19/06/2009**.

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

Millophyline-V 100 mg Oral Tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance	
Etamiphylline Camsilate	100 mg per tablet
Excipients	
Titanium Dioxide	1.50 mg per tablet
ponceau 4R Lake (E124)	2.08 mg per tablet

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablet.
Red coated biconvex tablet.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs and cats.

4.2 Indications for use, specifying the target species

Cardiac and respiratory stimulant. As an aid in the management of coughing, respiratory distress or cardiac conditions in dogs and cats.

May be used as an adjunct to antibiotic therapy.

4.3 Contraindications

Do not administer concomitantly with other CNS stimulants.

Do not use in animals less than 3 kg bodyweight.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i) Special precautions for use in animals

None.

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

Wash hands after use.

In the event of accidental ingestion, seek medical attention, taking the pack with you to show the doctor what has been taken.

iii) Other precautions

None.

4.6 Adverse reactions (frequency and seriousness)

Occasional central nervous system stimulation, which is readily countered by the use of a suitable hypnotic.

4.7 Use during pregnancy, lactation or lay

There is no, or inadequate, evidence of safety during pregnancy but the active substance has been in use for many years without apparent ill consequence. If drug therapy is required during pregnancy the drug should be the subject of a risk/benefit assessment by the veterinary practitioner.

4.8 Interaction with other medicinal products and other forms of interaction

Do not administer concomitantly with other CNS stimulants.

4.9 Amounts to be administered and administration route

For oral administration.

10 - 33	mg/kg:	bodyweight as follows:
3 - 10	kg:	one tablet every eight hours
11 - 20	kg:	one to two tablets every eight hours
21 - 30	kg:	two to three tablets every eight hours
31 - 40	kg:	four tablets every eight hours

Strict dosage according to bodyweight may need adjusting after assessing the clinical signs. In acute cases, treatment is best commenced by administration of the injectable preparation of etamiphylline camsilate, subsequent dosage being given orally. The length of treatment depends upon clinical response.

For long term use: after two weeks adjust the dosage, following assessment of the clinical signs, to the minimum compatible with achieving the alleviation of clinical signs.

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

Empty the stomach by emesis or gastric lavage. Administer activated charcoal. Treat hypokalaemia with intravenous infusions of potassium chloride. Administer diazepam intravenously to control convulsions.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Other systematic drugs for obstructive airway diseases.
ATC Vet Code: QR03DA06.

5.1 Pharmacodynamic properties

Etamiphylline camsilate is a cardiac and respiratory stimulant with the following actions:

Cardiovascular system
Increases cardiac amplitude without increasing rate; stimulates cardiac muscle; dilates coronary arteries, thus increasing blood flow.

Respiratory system
Increases rate and depth of respiration; relaxes smooth muscle of bronchi and bronchioles.
Spasmolytic.

Millophyline-V Tablets possess most of the properties of theophylline, but are soluble and relatively non-irritant to the gastric muscosa when given orally. The diuretic properties of Millophyline are low.

5.2 Pharmacokinetic properties

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Speedlake white 30019 (contains Titanium dioxide)
Ponceau 4R lake (E124)
Maize starch
Lactose monohydrate
Povidone (K30)
Magnesium stearate
Speed glaze 28698 (shellac)
Talc purified
Polyethylene glycol 4000 (lutrol E)
Sucrose
White beeswax
Carnuba wax

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.

6.4 Special precautions for storage

Do not store above 25ºC. Store in a dry place.

6.5 Nature and composition of immediate packaging

Polypropylene securitainer with tamper evident lid (push-fit). Pack sizes: 100 and 500 tablets.

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Dechra Limited
Dechra House
Jamage Industrial Estate
Talke Pits
Stoke-on-Trent
Staffordshire ST7 1XW
UK

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10799/010/001.

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19th June 2009

10 DATE OF REVISION OF THE TEXT