IRISH MEDICINES BOARD ACT 1995

ANIMAL REMEDIES REGULATIONS, 2005

(S.I. No. 734 of 2005)

VPA: **10988/064/002**
Case No: 7000270

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:

Virbac Laboratories

1 ere Avenue - 2065 m, **L.I.D.**, **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:

Pulmodox 60 mg/g oral paste for medium sized dogs

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 **15/01/2006** until **14/01/2011**.

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

Pulmodox 60 mg/g oral paste for medium sized dogs.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g Pulmodox Oral Paste contains:

Active substance(s):
Doxycycline (as hyclate form)..... 60 mg

Excipient(s):
Butylhydroxyanisole (E320)..... 0,18 mg

One syringe contains 10 g of paste

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral paste

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs

4.2 Indications for use, specifying the target species

Dogs weighing from 10 kg up to 20 kg:
Treatment of upper respiratory tract infections due to doxycycline susceptible strains of *Enterobacter spp, Escherichia coli, Klebsiella spp, Pasteurella spp, Pseudomonas spp, Staphylococcus spp, Streptococcus spp.*

4.3 Contraindications

Do not use in puppies before formation of tooth enamel

Do not use in dogs with known hypersensitivity to tetracyclines

4.4 Special warnings for each target species

The safety of the veterinary product has not been assessed in breeding animals.

4.5 Special precautions for use

Special precautions for use in animals
Pulmodox oral paste should be used based on susceptibility testing.

To be used cautiously in dogs with known hepatic insufficiency.

Special precautions to be taken by the person administering the medicinal products to animals
Wash hands after handling the product.

Do not handle this product if you are allergic to tetracyclines.

In case of accidental ingestion by a child, seek medical advice.

In case of eye contact, rinse abundantly with water.

If you develop symptoms following exposure such as skin rush, skin or eye irritation, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

4.6 Adverse reactions (frequency and seriousness)

Product administration can induce vomiting, salivation and yellowish coloration of the forming teeth enamel.

As for all tetracyclines, photosensitization in dogs with slight skin pigmentation as well as allergic reactions may exceptionally occur.

4.7 Use during pregnancy, lactation or lay

Studies performed in laboratory animals (rats, mice, rabbits) did not show any teratogenic, embryotoxic or maternotoxic effects of doxycycline at therapeutic doses.

The safety of the product in pregnant and nursing bitches has not been evaluated. Use of the product in pregnant or nursing bitches is not recommended.

4.8 Interaction with other medicinal products and other forms of interaction

The formation of doxycycline complexes with bivalent and trivalent cations is possible.
In the intestinal tract, concomitant administration of antacids and intestinal demulcents may lead to the formation of such complexes, resulting in the inhibition of the absorption of doxycycline. Such drugs should not be administered in conjunction with doxycycline, allowing at least two hours between administration.

Doxycycline may increase the action of anticoagulants.

Do not administer in conjunction with bactericidal antibiotics like ß-lactames.

4.9 Amounts to be administered and administration route

One daily oral administration of 10 mg of doxycycline per kg body weight, for 5 consecutive days. According to the double graduation system, each applicator division mark delivers enough paste to treat 10 or 15 kg bodyweight.

Dosage: one application division mark per 10 or 15 kg bodyweight per day for 5 consecutive days.

The product should be administered during meals.

To ensure a correct dosage, bodyweight should be accurately determined to avoid under-dosing

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

Dogs treated orally with doxycycline (as hyclate) at 2.5 and 5 times the recommended dose showed a dose dependent vomiting and salivation. No specific antidote for doxycycline is known, therefore in case of overdosage, symptomatic treatment should be given.

4.11 Withdrawal Period(s)

Not applicable

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: antibacterials for systemic use
ATCvet code: QJ01AA02

5.1 Pharmacodynamic properties

Doxycycline is a bacteriostatic antibiotic (acts by inhibiting protein synthesis) of the tetracycline family, obtained by hemi-synthesis (second-generation tetracycline). Doxycycline has the physico-chemical and pharmacodynamic properties of the tetracyclines. Doxycycline has a broad antibacterial spectrum.

The following bacteria have been shown to be sensitive to doxycycline: *Enterobacter spp, Escherichia coli, Klebsiella spp, Pasteurella spp, Pseudomonas spp, Staphylococcus spp, Streptococcus spp*

Resistance to doxycycline may be chromosomic or plasmidic, mediated either by bacterial cellular active efflux or ribosome protection. Although cross resistance between tetracyclines may occur, strains resistant to first generation tetracyclines can remain susceptible to doxycycline.

5.2 Pharmacokinetic properties

Following a single oral administration of the recommended dosage of 10 mg doxycycline per kg bodyweight, the bioavailability of doxycycline is about 51% and the plasmatic clearance is approximately 1 ml/min/kg. The maximum plasma concentration (4mg/L) is reached 3 hours after administration, and the elimination half-life is approximately 6 hours.

Doxycycline serum protein binding in dog is 82%. The active ingredient has a volume of distribution of 0.8 l/kg (Vss).

Doxycycline is eliminated through the digestive tract (75%) and urinary (25%) tract. The active ingredient is subject to an enterohepatic recirculation.

After repeated administration of the product at the recommended dosage of 10 mg/kg/day, the maximum plasma steady-state concentration is 5 mg/L. The minimum plasma steady-state concentration is 0.8 µg/ml. Average concentration between two successive administrations is 2.5 mg/L. The accumulation factor is 1.4.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxyanisole (E320)
Colloïdal anhydrous silica
Oleoyl macrogolglycerides

6.2 Incompatibilities

The formation of doxycycline complexes with bivalent Ca2+ and trivalent Fe3+ cations is possible.

6.3 Shelf-life

2 years.
After first opening of the container: 12 days

6.4 Special precautions for storage

The medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Nature of primary packaging:
- A high density polyethylene applicator.
- A graduated piston equipped with a low density polyethylene joint.
- A low density polyethylene stopper.

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

VIRBAC S.A.
1ère Avenue
2065 m - L.I.D.
06516 CARROS
FRANCE

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10988/64/2

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

15th January 2006