IRISH MEDICINES BOARD ACT 1995

ANIMAL REMEDIES REGULATIONS, 2005

(S.I. No. 734 of 2005)

VPA: **10966/019/002**
Case No: 7003097

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:

Vetoquinol UK Limited

Vetoquinol House, **Great Slade**, **Buckingham MK18 1PA**, **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:

Doxyseptin 300mg Tablet

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

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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

Doxyseptin 300 mg Tablet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Doxycycline (as Doxycycline hyclate 352.9mg)	300 mg

3 PHARMACEUTICAL FORM

Tablet

A red oblong film-coated tablet with a break mark.

4 CLINICAL PARTICULARS

4.1 Target Species

Dog.

4.2 Indications for use, specifying the target species

For the treatment of Doxycycline-sensitive systemic infections.

4.3 Contraindications

Do not use in cases of infection with doxycycline-resistant bacteria.
Do not use in animals with hepatic insufficiency.

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)

Vomiting, microbial superinfection of the gastro-intestinal tract and diarrhoea have been reported as side-effects following tetracycline therapy. After exposure to intensive sunlight or ultraviolet light photodermatitis may occur. Long term therapy may cause liver damage.

4.7 Use during pregnancy, lactation or lay

Due to the lower affinity to osteoid tissue than other tetracyclines no restrictions are recommended.

4.8 Interaction with other medicinal products and other forms of interaction

Doxycycline has a lower affinity to bivalent and trivalent cations than the older tetracyclines. With the exception of Fe^{3+} and Fe^{2+} the bioavailability is not significantly impaired by concomitant administration of metal cations.

The half-life of Doxycycline is reduced by concurrent administration of barbiturates (pento-, pheno-amylbarbiturates), ethanol and anti-epileptic drugs (carbamazepine, diphenylhydantoin).

Doxycycline should not be used concurrently with other antibiotics, especially bactericidal drugs such as ß-lactam antibiotics.

4.9 Amounts to be administered and administration route

10mg/kg orally, once daily, for up to 5 days.

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

None.

4.11 Withdrawal Period(s)

Not for use in animals intended for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Like all the other Tetracyclines, Doxycycline inhibits bacterial protein synthesis. They are broad-spectrum antibacterials active against *Mycoplasma*, *Chlamydia*, and *Rickettsia* as well as bacteria. Doxycycline is more lipophilic than the older tetracyclines and has a number of advantages. Absorption of orally administered Doxycycline is better and is less affected by milk and calcium salts. Doxycycline also penetrates better into several body compartments, notably the lung and cerebrospinal fluid. It enters the gastro-intestinal tract through the bile.

The range of action comprises particularly *Pasteurella spp.*, *Bordetella bronchiseptica*, *Staphylococcal spp.*, and *Streptococci*.

Doxyseptin 300 is well absorbed after oral administration. Peak plasma levels of Doxycycline are achieved within 2h with the recommended dose of 10mg/kg BW once daily. A half life ($t_{½\beta}$) of Doxycycline in dogs is about 12h after oral administration of Doxyseptin 300. Sufficient therapeutical plasma levels are maintained for 24h.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet Core
Lactose
Maize starch
Microcrystalline cellulose
Methylhydroxyethylcellulose
Colloidal anhydrous silica
Magnesium stearate

Coating
Talc
Titanium dioxide
Propylene glycol
Sicovit Cochineal red lake E124
Eudragit RL PO 100 (dry weight)
Macrogol 6000
Purified Water

6.2 Incompatibilities

None.

6.3 Shelf-life

The shelf life of the product is 36 months.

6.4 Special precautions for storage

Do not store above 25°C, store in a dry place.

6.5 Nature and composition of immediate packaging

Blister of two foils: base layer foil of PVC/PVdC and a push through foil of aluminium. One blister strip contains 10 film coated tablets. Cartons contain 20, 100, 250 and 500 film-coated tablets.

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

Vetoquinol UK Limited,
Vetoquinol House,
Great Slade,
Buckingham Industrial Park,
Buckingham,
MK18 1PA,
United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10966/19/2

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10th December 2004

10 DATE OF REVISION OF THE TEXT

31st July 2006

12th January 2007