IRISH MEDICINES BOARD ACT 1995

ANIMAL REMEDIES REGULATIONS, 2005

(S.I. No. 734 of 2005)

VPA: **10966/015/001**
Case No: 7002006

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:

Ampitab 50mg Coated 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.

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

Ampitab 50 mg Coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains:

Active substance			
Ampicillin trihydrate		57.75	mg
(equivalent to Ampicillin 50mg)			
in a formulation also containing:			
Excipients			
Lactose monohydrate		21.10	mg
Maize starch		5.00	mg
Microcrystalline cellulose		24.45	mg
Colloidal anhydrous silica		2.70	mg
Magnesium stearate		3.00	mg
Talc	Ph. Eur.	2.331	mg
Titanium dioxide		0.538	mg
Macrogol 6000		0.717	mg
Polyacrylate dispersion 30%		0.914	mg
(Poly (ethyl acrylate, methyl methacrylate) dispersion 30%)			
Eudragit NE 30D			

For a full list of excipients see 6.1

3 PHARMACEUTICAL FORM

Coated Tablet
A white, round, biconvex film coated tablet, intended for oral use.

4 CLINICAL PARTICULARS

4.1 Target Species

Dog

4.2 Indications for use, specifying the target species

For the use in infections of the respiratory, gastro-intestinal and genito-urinary tract and skin/soft tissue due to bacteria susceptible to Ampicillin.

4.3 Contraindications

Not to be administered to animals known to be sensitive to β-lactam antibiotics or in case of infections caused by ampicillin-resistant bacteria.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precaution(s) for use in animals

None.

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

Penicillins and cephalosporins may cause sensitisation (allergy) following ingestion, inhalation or skin contact. Sensitivity to penicillin may lead to cross-sensitivity to cephalosporins and vice versa. Allergic reactions to these substances are occasionally serious. Operators with known hypersensitivity should not handle these drugs.

1. Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.

2. Handle this product with great care to avoid exposure, taking all recommended precautions.

3. If you develop symptoms following exposure, such as a skin rash, you should seek medical advice and show the doctor this warning.

Swelling of the face, lips or eyes or difficulty breathing are more serious symptoms and require urgent medical attention.

4.6 Adverse reactions (frequency and seriousness)

Allergic reactions (skin, anaphylactoid reactions) are rare.

Diarrhoea in rare cases.

4.7 Use during pregnancy, lactation or lay

The product may be given to pregnant and lactating dogs.

4.8 Interaction with other medicinal products and other forms of interaction

Ampicillin should not be administered with bacteriostatic antibiotics because the combination may reduce the bactericidal activity of the ampicillin.

4.9 Amounts to be administered and administration route

For oral administration.

25mg/kg b.w., three times daily.
Corresponding to 1 tablet AMPITAB 50 mg per 2 kg bodyweight t.i.d.
The minimal duration of treatment should be 5 days.
The tablets should be administered on an empty stomach.

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

When administered in amounts representing five times the normal dose, ampicillin is well tolerated.

In case of overdosing fluid therapy should be initiated.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

The bio-availability of ampicillin in dogs is reported as ca. 50%. After administration of the recommended oral dose of 10mg/kg b.w. a C_{max} of 1.46 microg/ml is achieved. The mean T_{max} is 1.85 hours. The mean value for elimination half-life is 1.4 hours.
Ampicillin has an in vivo bactericide action with a broad spectrum of antibiotic activity against gram-positive and gram-negative bacteria provided they are sensitive to ampicillin; e.g. infections in dogs caused by the following bacteria; Streptococcus spp., Pasteurella spp., Staphylococcus aureus and other pathogenic staphylococci.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Maize starch
Microcrystalline cellulose
Colloidal anhydrous silica
Magnesium stearate
Talc
Titanium dioxide
Macrogol 6000
Polyacrylate dispersion 30%
(Poly (ethyl acrylate, methyl methacrylate) dispersion 30%)
Eudragit NE 30D

6.2 Incompatibilities

None known

6.3 Shelf-life

The shelf-life is 2 years from the date of manufacture.

6.4 Special precautions for storage

Store below 25°C in a dry place.

6.5 Nature and composition of immediate packaging

Two blister strips, each containing 12 tablets. Base layer of PVC/PVDC, push through foil of aluminium.

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

Vetoquinol (UK) Ltd.,
Vetoquinol House
Great Slade
Buckingham Industrial Park
Buckingham
MK18 1PA
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10966/15/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

22nd January 2004