IRISH MEDICINES BOARD ACT 1995

MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998

(S.I. No.142 of 1998)

10996/059/003
Case No: 7002393

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Intervet Ireland Limited

Magna Drive, **Magna Business Park**, **Citywest Road**, **Dublin 24**, **Ireland**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Amfipen Tablets 500 mg

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **15/12/2006** until .

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Amfipen Tablets 500 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance	quantity per tablet
Anhydrous Ampicillin	500 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Tablets.

4 CLINICAL PARTICULARS

4.1 Target Species

Cats and dogs.

4.2 Indications for use, specifying the target species

For the treatment and prevention of infections in dogs and cats caused by the following bacteria provided they are sensitive to ampicillin:
Streptococcus spp, Actinomyces pyogenes, Pasteurella haemolytica, P. multocida, Staphylococcus aureus and other pathogenic *Staphylococc*i.

4.3 Contraindications

Not to be administered to animals sensitive to penicillin.
Not to be used in rabbits, guinea pigs, hamsters, gerbils or in any other small herbivores.
Not effective against beta-lactamase producing organisms.

4.4 Special warnings for each target species

Not to be used in animals allergic to ampicillin.

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

Penicillin and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillin may lead to cross reactions to cephalosporins and vice versa. Allergic reactions to these substances are occasionally serious.
Do not handle this product if you know you are sensitised or if you have been advised not to work with such preparations.
Handle this product with great care to avoid exposure, taking all recommended precautions.
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 with breathing are more serious symptoms and require urgent medical attention.

4.6 Adverse reactions (frequency and seriousness)

Allergic reactions have been observed occasionally.

4.7 Use during pregnancy, lactation or lay

No special precautions necessary.

4.8 Interaction with other medicinal products and other forms of interaction

Antagonism between Amfipen tablets and bacteriostatic preparations may occur. Resistant bacteria might emerge that show a cross-resistance to other beta-lactam antibiotics.

4.9 Amounts to be administered and administration route

To be given by the oral route only.
Cats 10-20 mg/kg twice daily using either 50 mg or 125 mg tablets.
Dog 10-20 mg/kg twice daily using either 50 mg, 125 mg or 500 mg tablets.
The higher dose levels are advised when treating infections due to Gram-negative bacteria and in cases involving young animals. Therapy should be repeated every 12 hours and continued for a maximum of 5 days. In severe or acute conditions in dogs and cats only, the dose levels may be increased.
In small animals tablets should be given on an empty stomach.

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

Not applicable.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Ampicillin is a beta-lactam antibiotic which has bactericidal activity against mainly Gram-positive bacteria and some Gram-negative aerobes. It is sensitive to beta-lactamase (penicillinase) inactivation. It is widely distributed in the extra-cellular fluids after absorption, and eliminated almost entirely by the kidneys.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline Cellulose
Povidone K30
Polacrilin Potassium
Magnesium Stearate
Lactose Monohydrate

6.2 Incompatibilities

None known.

6.3 Shelf-life

2 years.

6.4 Special precautions for storage

White polypropylene securitainer with polyethylene lid.
In packs of 30 x 500 mg.

6.5 Nature and composition of immediate packaging

White polypropylene securitainer with polyethylene lid.
In packs of 30 x 500 mg.

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

Intervet Ireland Ltd.,
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/59/3

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2002