IRISH MEDICINES BOARD ACT 1995

ANIMAL REMEDIES REGULATIONS, 2005

(S.I. No. 734 of 2005)

VPA: **10019/042/001**
Case No: 7002014

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:

Pfizer Healthcare Ireland

Trading as Pfizer Animal Health, **Ringaskiddy**, **Co. Cork**, **Ireland**

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:

Clamoxyl Palatable Tablets 40mg

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

Clamoxyl Palatable Tablets 40 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:
Active Substance
Amoxicillin (as amoxicillin trihydrate) 40 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs and cats.

4.2 Indications for use, specifying the target species

Clamoxyl is a broad spectrum semi-synthetic penicillin which is bactericidal against a wide range of Gram-positive and Gram-negative bacteria found in dogs and cats and including the following:

Haemophilus spp., *Pasteurella* spp., *Proteus mirabilis*, *Salmonella* spp., *Staphylococcus* spp. (penicillin-sensitive strains), *Leptospira* spp., *Streptococcus* spp. and *Escherichia coli.*

When susceptible organisms are present, Clamoxyl may be effective in the following indications: localised infections, alimentary tract infections, respiratory infections, urogenital tract infections, secondary bacterial infections and generalised infections.

4.3 Contraindications

In common with all penicillins, Clamoxyl should not be given to penicillin-sensitive animals.
Clamoxyl should not be used orally or parenterally in rabbits, guinea pigs, hamsters or gerbils. Caution is advised in its use in any other very small herbivores.

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

Operator warning

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion, or skin contact.

Hypersensitivity to penicillins may lead to cross-reactions to cephalosporins and *vice versa*. Allergic reaction to these substances may occasionally be 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 breathing are more serious symptoms and may require urgent medical attention.

4.6 Adverse reactions (frequency and seriousness)

See 5.8.

4.7 Use during pregnancy, lactation or lay

Clamoxyl Palatable Tablets may be used safely in pregnant or lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Dosage Rate:

An oral dose rate of 4 to 10 mg/kg (2 to 5 mg/lb) twice daily is recommended. In severe or acute conditions, these levels may be increased and/or repeated at more frequent intervals.

Dosage Guide:

Cats: ½ - 1 tablet twice daily
Dogs per 10 kg: one or two tablets, twice daily
The tablets are often accepted from the hand, even by sick animals. Alternatively, the tablets may be crushed and added to a little food.

Because of the high blood levels rapidly achieved after oral dosing parenteral antibiotic treatment has generally been found to be unnecessary even in the presence of systemic diseases. However, where parenteral treatment is required, the tablets may be used as follow-up therapy.

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

Clamoxyl is of a low order of toxicity to the target species and is well tolerated by the oral route. Apart from occasional instances of diarrhoea, which have been reported at the recommended dose, no adverse side effects are to be expected from accidental overdose.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Bactericidal against a wide range of Gram-negative and Gram-positive bacterial pathogens found in dogs and cats including the following:
Haemophilus spp
Pasteurella spp
Proteus mirabilis
Salmonella spp
Staphylococcus spp. (penicillin-sensitive strains)
Leptospira spp.
Streptococcus spp.
Escherichia coli.

After absorption amoxicillin is widely distributed throughout the tissue with especially high levels in the kidney, urine, liver and bile.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium Stearate
Colloidal Anhydrous Silica
Yeast, roller dried
Methylcellulose
Microcrystalline Cellulose (dried)

6.2 Incompatibilities

None known.

6.3 Shelf-life

2 years.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Blister packs containing 100 x 40 mg Clamoxyl Palatable 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

Pfizer Healthcare Ireland
Trading as Pfizer Animal Health
Ringaskiddy
County Cork
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10019/42/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2002