

**IRISH MEDICINES BOARD ACT 1995**

**EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007**

**(S.I. No. 786 of 2007)**

VPA: **10047/013/001**

Case No: 7004284

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

**Elanco Animal Health, Eli Lilly and Company Limited**

**Priestly Road, Basingstoke, Hampshire RG24 9NL, England**

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:

**Apralan G100 Premix**

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 revoked, shall continue in force from **30/06/2008** until **30/09/2008**.

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

APRALAN G 100 Premix

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each kg contains:

Active Substance

Apramycin Sulphate

equivalent to 100 g apramycin activity

For a full list of excipients see section 6.1.

#### 3 PHARMACEUTICAL FORM

Premix for medicated feed.

#### 4 CLINICAL PARTICULARS

##### 4.1 Target Species

APRALAN G 100 Premix is indicated for use in young pigs.

##### 4.2 Indications for use, specifying the target species

For the treatment and control of bacterial enteritis in young pigs caused by *Escherichia coli* and other apramycin sensitive organisms. In vitro, the following organisms were susceptible to apramycin at concentrations of 16µ/ml or less;

i) Gram-positive bacteria  
*Staphylococcus aureus*.

ii) Gram-negative bacteria

*Bordetella bronchiseptica*

*Echerichia coli*

*Campylobacter* spp

*Klebsiella* spp

*Salmonella* spp

*Proteus* spp

*Pseudomonas aeruginosa*

*Shigella sonnei*.

iii) *Mycoplasma*

*Mycoplasma hyponeumoniae*.

### **4.3 Contraindications**

Do not use in cases of known hypersensitivity to apramycin.  
Do not use in cats.

### **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**

Avoid contact with skin and eyes. In the event of skin or eye contact, wash the affected area thoroughly with water.  
Wash hands after use.

### **4.6 Adverse reactions (frequency and seriousness)**

None known.

### **4.7 Use during pregnancy, lactation or lay**

APRALAN g 100 Premix is not intended for use in pregnant or lactating animals. However, laboratory studies in the rat and rabbit have not produced any evidence of a teratogenic effect.

### **4.8 Interaction with other medicinal products and other forms of interaction**

None observed.

### **4.9 Amounts to be administered and administration route**

For oral administration. The dose is 4-8 mg kg bodyweight. To achieve this, thoroughly mix 1 kg of Apralan G 100 Premix in one tonne of finished feed to provide 100 ppm apramycin activity. To ensure thorough dispersion, 1 kg of Apralan G 100 Premix should first be mixed with 20 kg of feed before incorporation into the finished feed. The product can be incorporated into pelleted feed preconditioned with steam for up to 15 minutes at a temperature of not greater than 75°C. Feed as the only ration for a maximum of 28 days or as directed by the Veterinary Surgeon. Only to be incorporated by a manufacturer who is approved to mix at a rate of below 2kg per tonne of final feed.

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

Groups of five male and five female four-week old pigs received apramycin ad libitum in the feed at up to 550 ppm for 28 days. No reactions were detected.

### **4.11 Withdrawal Period(s)**

Treated pigs must not be slaughtered for human consumption during treatment or for at least 14 days after the last treatment.

## 5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Apramycin is a broad -spectrum aminocyclitol antibiotic produced by a strain of *Streptomyces tenebrarius*. Apramycin is bactericidal at minimum inhibitory concentrations.

### 5.1 Pharmacodynamic properties

Apramycin is effective against both Gram-negative and Gram-positive bacteria and some strains of mycoplasma at concentrations of 16 µg/ml or less. It is effective against most field strains of *Escherichia coli* and *salmonellae*

### 5.2 Pharmacokinetic properties

The oral administration of apramycin is intended for antimicrobial activity within the gut; apramycin is poorly absorbed, particularly in older animals.

#### Absorption:

Pigs. Nine mg of apramycin/kg bodyweight administered orally is well absorbed in 2 day old pigs, slightly absorbed in 4 week old pigs and not absorbed in 8- week old pigs.

Calves. Serum levels peak at approximately 6 hours with a value of 2.4 µl/ml following oral administration of 40mg apramycin/kg bodyweight. Duration of serum activity is between 24 and 36 hours.

Distribution, Biotransformation and Excretion; Pigs, Very little metabolism of apramycin takes place in the animal.

Dosing 10 kg pigs with <sup>14</sup>C apramycin resulted in approximately 83% being recovered from the faeces, and 4 % from the urine, as <sup>14</sup>C apramycin.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Antidusting Oil  
Soybean mill run or rice hulls

### 6.2 Incompatibilities

None known.

### 6.3 Shelf-life

The shelf life of Apralan G100 premix is 36 months.

The product will remain stable in the finished feed and in pelleted feed for 3 months.

### 6.4 Special precautions for storage

Multiwalled paper sacks: Do not store above 25°C. Store in a dry place.

Flexible laminate bag: Store in a dry place.

## **6.5 Nature and composition of immediate packaging**

Apralan G100 Premix is presented in:

- (i) 5kg and 25kg polythene lined multiwalled paper sacks
- (ii) 5kg and 25 kg flexible laminate bags with aluminium foil layer.

## **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**

Eli Lilly and Company Ltd.,  
Elanco Animal Health,  
Priestly Road,  
Basingstoke,  
Hampshire RG 24 9NL,  
England.

## **8 MARKETING AUTHORISATION NUMBER(S)**

VPA 10047/13/1

## **9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

1<sup>st</sup> October 2003

## **10 DATE OF REVISION OF THE TEXT**

30th June 2008