SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Apralan G200 Premix for Medicated Feeding Stuff

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Apramycin (as apramycin sulphate) 200g apramycin per kg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuff.

Light tan granular free flowing premix

4. CLINICAL PARTICULARS

4.1 Target species

Apralan G200 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 16 µg/ml or less:
i) Gram-positive bacteria
Staphylococcus aureus.

ii) Gram-negative bacteria
Bordetella bronchiseptica
Escherichia coli
Campylobacter spp
Klebsiella spp
Salmonella spp
Proteus spp
Pseudomonas aeruginosa
Shigella sonnei

iii) Mycoplasma
Mycoplasma hyopneumoniae

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

i. Special precautions for use in animals

Official, national and regional antimicrobial policies should be taken into account when the product is used.

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

Avoid inhaling the powder while preparing the medicated feed.
Avoid contact with skin and eyes. In the event of skin contact, wash thoroughly with soap and water.
In the event of accidental eye contact, wash the affected eye with fresh running water and seek medical attention if irritation persists. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Apralan G200 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 0.5 kg of Apralan G200 Premix in one tonne of finished feed to provide 100 ppm apramycin activity. It is recommended to first thoroughly mix 1 part of product to 20 parts of feed (e.g. 0.5 kg of Apralan G200 Premix to 10 kg 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.

The intake of medicated feed depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of Apralan G200 has to be adjusted accordingly.

Feed as the only ration for a maximum of 28 days or as directed by the veterinary surgeon.

For incorporation into dry feed at the registered mill.
A manufacturer who is approved to incorporate directly at any concentration, veterinary medicinal products or premixtures containing such products must be responsible for mixing when incorporation is less than 2kg per tonne for 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)

Meat: 14 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, Aminoglycoside antibacterials, Other amnioglycosides

ATCvet code: QJ01GB90

5.1 Pharmacodynamic properties

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

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 particulars

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 40 mg 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 ^{14}C apramycin resulted in approximately 83% being recovered from the faeces, and 4% from the urine, as ^{14}C apramycin.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Pregelatinized starch
Solvent extracted soybean feed special

6.2 Incompatibilities

None known.

6.3 Shelf life

The shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after incorporation into meal or pelleted feed: 3 months.

6.4. Special precautions for storage

Bags i) and iii) Do not store above 25°C. Store in a dry place.
Bag ii) Store in a dry place.

6.5 Nature and composition of immediate packaging

Apralan G200 is presented in 5 and 25 kg packs in either of:

i) polythene lined multiwalled paper bags
ii) flexible laminate bag with aluminium foil layer
iii) polypropylene tote bags

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with national requirements

7. MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

8. MARKETING AUTHORISATION NUMBER

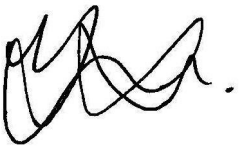
Vm 00879/4167

9. DATE OF FIRST AUTHORISATION

6 April 1998

10. DATE OF REVISION OF THE TEXT

September 2020



Approved: 24 September 2020