

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

BACK LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Apralan G200 Premix for medicated feeding stuff G: Granular.

2. STATEMENT OF ACTIVE SUBSTANCES

Apramycin (as apramycin sulphate) 200 g per kg (200 units per mg)

3. PHARMACEUTICAL FORM

Premix

4. PACKAGE SIZE

Apralan G200 is supplied in bags containing 5 kg and 25 kg of product. Not all pack sizes may be marketed.

5. TARGET SPECIES

Pigs

6. INDICATION(S)

For the treatment and control of bacterial enteritis in young pigs caused by *Escherichia coli* and other organisms susceptible to apramycin. Official, national and regional antimicrobial policies should be taken into account when the product is used.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Incorporate the product at a rate of 0.5 kg per tonne to give 100 g apramycin per tonne of complete feed (100 ppm) to provide 4-8 mg apramycin/kg bodyweight. Feed as the only ration for a maximum period of 28 days. The intake of medicated feed depends on the clinical condition of the animals. In order to obtain correct dosage, the concentration of Apralan G200 Premix for medicated feedingstuff has to be adjusted.

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. (e.g. 0.5 kg Aprlan G200 Premix to 10 kg feed) before incorporation into the finished feed.

8. WITHDRAWAL PERIOD (S)

Meat 14 days.

9. SPECIAL WARNING(S), IF NECESSARY

OPERATOR WARNING

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.

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

CONTRA-INDICATIONS

Do not use in known cases of hypersensitivity.

Toxic to cats.

10. EXPIRY DATE

Use Before:

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with national requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE,

For animal treatment only.

To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

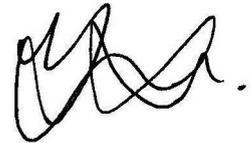
Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4167

VPA 10047/13/2

17. MANUFACTURER'S BATCH NUMBER

A handwritten signature in black ink, consisting of several loops and a final flourish.

Approved: 24 September 2020