PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

BAG OF 1 KG

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetipracin 250 000 IU/g powder for use in drinking water/milk.

2. COMPOSITION

Each g contains:

Active substance:
Apramycin sulfate ……250 000 IU

Cream colour powder.

3. PACKAGE SIZE

1 kg

4. TARGET SPECIES

Pig (weaned piglet), cattle (pre-ruminant), chicken (broiler) and rabbit.

5. INDICATIONS FOR USE

Indications for use
Pig (weaned piglet):
Treatment of bacterial enteritis caused by *Escherichia coli* susceptible to apramycin.

Cattle (pre-ruminant):
Treatment of bacterial enteritis caused by *Escherichia coli* and clinical outbreaks due to *Salmonella enterica* subsp. *enterica* serovar Dublin (*Salmonella* Dublin) susceptible to apramycin. Treatment should be based on prior confirmation of the *Salmonella* serovars involved or at least the availability of epidemiological data confirming the presence of this serovar.

Chicken (broiler):
Treatment of colibacillosis caused by *Escherichia coli* susceptible to apramycin.

Rabbit:
Treatment and metaphylaxis of bacterial enteritis caused by *Escherichia coli* susceptible to apramycin.
The presence of the disease in the herd must be established before the product is used.

6. CONTRAINDICATIONS

Contraindications
Do not use in case of hypersensitivity to apramycin or to any of the excipients.
Do not use in calves with functional rumen.
Do not use in animals suffering from kidney disorders.

7. SPECIAL WARNINGS

Special warnings

Cross resistance has been shown between apramycin and gentamicin antibiotics. Use of the product should be carefully considered when susceptibility testing has shown resistance to aminoglycoside antibiotics because its effectiveness may be reduced.

Special precautions for safe use in the target species:
Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.
Where a diagnosis of *Salmonella Dublin* is made on the farm, then control measures including on-going monitoring of disease status, vaccination, biosecurity and movement controls should be considered. National control programmes should be followed where available.
Use of the veterinary medicinal product deviating from the instructions given in the Summary of product characteristics may increase the prevalence of bacteria resistant to the apramycin and may decrease the effectiveness of treatment with aminoglycosides due to the potential for cross-resistance.

Use of the product should be in accordance with official, national and regional antimicrobial policies.

An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

The uptake of medication by animals can be altered as a consequence of illness. In case of insufficient uptake of water/milk animals should be treated parenterally using a suitable injectable veterinary medicinal product following the advice of the veterinarian.

Animals with acute or severe clinical conditions that cannot drink, should receive adequate parenteral treatment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to apramycin or any other aminoglycoside should avoid contact with the veterinary medicinal product.
This product may cause irritation or sensitisation after skin or eye contact or inhalation.
Avoid contact with the eyes, skin and mucous membranes and inhalation of dust while preparing the medicated water/milk.
Use personal protective equipment consisting of gloves, mask, goggles and protective clothing while handling the product.
Wash hands after use.
In case of eye contact, rinse the affected area with plenty of water. In case of skin contact, wash thoroughly with soap and water. If irritation persists, seek medical advice.
In the case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
In case of onset of symptoms after exposure such as skin rash, seek medical advice immediately and show the package leaflet or the label to the physician. Swelling of the face, lips and eyes or difficult breathing are more serious symptoms and require urgent medical assistance.

Pregnancy and lactation:
Pig:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation in sows. Use only according to the benefit-risk assessment by the responsible veterinarian.

Cattle:
The use is not intended during pregnancy or lactation.

Rabbit:
Oral doses of apramycin administered from 6th to the 18th day of pregnancy (including doses below the therapeutic doses), have shown evidence of foetotoxic effects. Do not use during pregnancy.

Laying birds:
Chicken:
Do not use in birds in lay and within 4 weeks before the start of the laying period.

Interactions with other medicinal products and other forms of interaction:
Aminoglycosides may have a negative influence on the kidney function. The administration of aminoglycosides to animals suffering from renal impairment or in combination with substances that also affect renal function may therefore present a risk of intoxication.
Aminoglycosides may cause neuromuscular blockade. It is therefore recommended to take such an effect into account when anaesthetising treated animals.

Overdose:
Pig: Pigs have been given up to nine times the recommended use level in their drinking water for 28 days with no untoward reaction.

Cattle: Calves were given apramycin in milk replacer daily for five days, at doses up to 120 mg/kg of bodyweight. There was no toxic effect.

Chicken: There was no mortality when chickens were given a single oral dose of 1,000 mg/kg of bodyweight. Chickens were given up to 5 times the recommended level for 15 days with no untoward reaction.

Possible intoxications can be recognised by the following symptoms: soft faeces, diarrhoea, vomiting (weight loss, anorexia, and similar), renal impairment and effects on the central nervous system (reduced activity, loss of reflexes, convulsions, etc.).

Do not exceed the recommended dose.

Special restrictions for use and special conditions for use:
[ES]: Administration conditions: To be administered by a veterinary surgeon or under their direct responsibility.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

No information is available on potential interactions or incompatibilities of this veterinary medicinal product administered orally by mixing into drinking water or liquid feed containing biocidal products, feed additives or other substances used in drinking water.

8. ADVERSE EVENTS

Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked,

please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details on this label, or via your national reporting system {national system details}.

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

Administration route:
To be administered via the drinking water. Drinking systems should be clean and free of rust to avoid reduction of activity.
In cattle (pre-ruminant) it can be administered in milk replacer.

Amounts to be administered:
Pig (weaned piglet):
Administer 12,500 IU apramycin sulfate per kilogram of bodyweight (corresponding to 50 mg of product/kg bw), daily for 7 consecutive days.

Cattle (pre-ruminant):
Administer 40,000 IU apramycin sulfate per kilogram of bodyweight (corresponding to 160 mg of product/kg bw), daily for 5 consecutive days.

Chicken (broiler):
Administer 80,000 IU apramycin sulfate per kilogram of bodyweight (corresponding to 320 mg of product/kg bw), daily for 5 consecutive days.

Rabbit:
Administer 20,000 IU apramycin sulfate per kilogram of bodyweight (corresponding to 80 mg of product/kg bw), daily for 5 consecutive days.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration
To ensure a correct dosage, body weight should be determined as accurately as possible.

The use of suitably calibrated measuring equipment is recommended.

The intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dose, the concentration of the veterinary medicinal product has to be adjusted accordingly.

Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{\text{mg veterinary medicinal product / kg body weight day} \times \text{Average body weight (kg) of animals to be treated}}{\text{Average daily water intake (l/animal)}} = \text{mg veterinary medicinal product per litre of drinking water/milk}$$

Medicated water should be the only source of drinking. Medicated water must be renewed every 24 hours. Solutions in reconstituted milk replacer should be prepared immediately before use.

The maximum solubility of the powder is 25 000 IU of apramycin/ml (100 g of product / 1 L of water).

Water uptake should be monitored at frequent intervals during medication. In order to ensure consumption of the medicated water, animals should not have access to other water supplies whilst being treated. After the end of the medication period, the water supply system should be cleaned appropriately to avoid intake of sub-therapeutic amounts of the active substance.

Do not use Vetipracin 250 000 IU/g powder for use in drinking water/milk if you notice visible signs of deterioration.

11. WITHDRAWAL PERIODS

Withdrawal periods
Pig:
Meat and offal: Zero days.

Cattle:
Meat and offal: 28 days.

Chicken:
Meat and offal: Zero days.
Not for use in birds producing or intended to produce eggs for human consumption. Do not use within 4 weeks before the start of the laying period.

Rabbit:
Meat and offal: Zero days.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the bag after EXP. The expiry date refers to the last day of that month.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater <or household waste.>

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Pack sizes
Bag of 1 kg.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

17. CONTACT DETAILS

Marketing authorisation holder and manufacturer responsible for batch release <and contact details to report suspected adverse reactions>:

Laboratorios Maymó, S. A.U.
Vía Augusta, 302.
08017 Barcelona

Local representatives <and contact details to report suspected adverse reactions>:

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder listed below.>

18. OTHER INFORMATION

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Shelf life after first opening the immediate packaging: 6 months.
Shelf life after dissolution in drinking water according to directions: 24 hours.
Shelf life after dissolution in milk replacer according to directions: use inmediately.

21. BATCH NUMBER

Lot {number}