



Composition

Active substance: **Apramycin 552 IU* / mg**

(as apramycin sulfate)

*IU – international units

Excipients: None

Pharmaceutical form

Powder for use in drinking water/milk.

Almost white to yellow powder.

Target species

Pigs (weaned piglets), **cattle** (pre-ruminant calves), **chickens** (broilers) and **rabbits**.

Indications

Pigs (weaned piglets): Treatment of bacterial enteritis caused by *Escherichia coli* susceptible to apramycin.

Pre-ruminant calves: 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.

Chickens: Treatment of colibacillosis caused by *Escherichia coli* susceptible to apramycin.

Rabbits: 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.

Practical dosing and administration

To be administered via the drinking water. Drinking systems should be clean and free of rust to avoid reduction of activity.

In the case of calves it can be administered in milk or milk replacer.

Amounts to be administered:

Pigs:

- Administer 12,500 IU apramycin sulfate per kilogram of bodyweight (corresponding to 22.5 mg of product/kg bw), daily for 7 consecutive days.

Calves:

- Administer 40,000 IU apramycin sulfate per kilogram of bodyweight (corresponding to 72 mg of product/kg bw), daily for 5 consecutive days.

Chickens:

- Administer 80,000 IU apramycin sulfate per kilogram of bodyweight (corresponding to 144 mg of product/kg bw), daily for 5 consecutive days.

Rabbits:

- Administer 20,000 IU apramycin sulfate per kilogram of bodyweight (corresponding to 36 mg of product/kg bw), daily for 5 consecutive days.

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.

The amount of product (mg) to be incorporated per 1 l of water or milk should be established according to the following formula:

Dose (mg product per kg body weight per day)	X	mean body weight (kg) of animals to be treated	=	mg of the product per litre of drinking water /milk
Average daily water intake (l/animal)				

Withdrawal period

Pigs: Meat and offal: **Zero days.**

Calves: Meat and offal: **28 days.**

Chickens: 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** of the start of the laying period.

Rabbits: Meat and offal: **Zero days.**

Shelf life and storage

- Shelf life
 - of the veterinary medicinal product as packaged for sale: 2 years.
 - after first opening the immediate packaging (bottle and bag): 28 days.
 - after first opening the immediate packaging (sachet): Use immediately.
 - after dilution in drinking water: 24 hours.
 - after dilution in milk replacer: Use immediately.
- Store below 25°C.

Packaging

- High density polyethylene bottles with polypropylene screw caps
- Cardboard box containing 25 or 50 Polyethylene/aluminium/polypropylene foiled sachets
- Block bottom zipped polyethylene/aluminium/polyethylene terephthalate laminated bags
- Bottles containing 90.58 g of apramycin sulfate or 50 000 000 IU.
- Sachets containing 1.812 g of apramycin sulfate or 1 000 000 IU.
- Bags containing 1811.6 g of apramycin sulfate or 1 000 000 000 IU.
- Not all pack sizes may be marketed.



Contraindications

Do not use in known cases of hypersensitivity to the active substance or to any of the excipients.

- Full SPC can be obtained on request
- Indications listed above are not necessarily authorized in all countries. Please consult the local label for exact indications and posology.
- Use medicines responsibly.
- POM-V
- Vm 30282/4030

