SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Apravet 100 g/kg premix for medicated feeding stuff for pigs.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each kg contains:

Active substance:
Apramycin sulfate 100 g equivalent to apramycin 100.000.000 IU.

Excipients:

Qualitative composition of excipients and other constituents
Starch, pregelatinised
Wheat meal

Light brown granules.

3. CLINICAL INFORMATION

3.1 Target species

Pigs.

3.2 Indications for use for each target species

Treatment and metaphylaxis of bacterial enteritis caused by micro-organisms susceptible to apramycin such as *Escherichia coli.*

The presence of the disease in the group must be established before the veterinary medicinal product is used.

3.3 Contraindications

Do not use in the cases of hypersensitivity to the active substance, to other aminoglycosides or to any of the excipients.
Do not use in animals suffering from kidney disorders.
Do not use in cats.

3.4 Special warnings

The uptake of medication by animals can be altered as a consequence of illness. In case of insufficient uptake of feed animals should be treated parenterally.
The use of the veterinary medicinal product should be combined with good management practices e.g. good hygiene, proper ventilation, no overstocking.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use of the veterinary medicinal product should be based on 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.

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

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

People with known hypersensitivity to apramycin should administer the veterinary medicinal product with caution.
During preparation and administration of the medicated feedingstuff, skin, eye and oral contact with the veterinary medicinal product, as well as inhalation of dust, should be avoided. Personal protective equipment consisting of suit, gloves and an appropriate dust mask (either a disposable half mask respirator conforming to European Standard EN149 or a non-disposable respirator conforming to European Standard EN140 with a filter to EN 143) should be worn when handling the veterinary medicinal product.
Wash any contaminated skin. Wash hands carefully with soap and water after handling of the veterinary medicinal product. In the event of accidental ingestion, seek medical assistance immediately and show the package label.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigs:

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Laboratory studies have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects.
The use is not recommended in pregnant or lactating sows.

3.8 Interaction with other medicinal products and other forms of interaction

In certain conditions with a high degree of humidity there might be an apparent interaction with lectins.
Aminoglycosides may have a negative influence on the kidney function. The administration of these agents to animals suffering from renal impairment or in combination with agents that also affect renal function may therefore present a risk of intoxication.

Do not administer with other aminoglycosides due to their nephrotoxic potential.
Aminoglycosides may cause neuromuscular blockade. It is therefore recommended to take such an effect into account when anaesthetising treated animals.

3.9 Administration routes and dosage

In feed use.

The dosage is 4 000-8 000 IU apramycin/kg of bodyweight per day (equivalent to 4-8 g of the veterinary medicinal product per 100kg of bodyweight per day).
Administer as the sole feeding stuff for at least 21 days. It is recommended to mix the required quantity of the veterinary medicinal product with a small amount of feed (20 – 50 kg) before mixing it in the total volume.

The intake of medicated feed depends on the clinical condition of the animals. In order to obtain the correct dosing, the concentration of apramycin may need to be adjusted accordingly.

To adjust dosing properly the following calculation can be used:

$$\frac{\text{… g product/kg b.w./day} \times \text{average b.w. of pigs (kg)}}{\text{average daily intake of feed (kg/animal)}} = \text{… g of the product/kg of feed}$$

Medicated feed may be pelleted using a pre-conditioning step for 5 minutes at a temperature not exceeding 85°C.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

A single 100 fold overdosing in 5 pigs did not result in any mortality.
A 25 to 50 fold overdosing during 28 days, did not provoke any toxic effect.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

This veterinary medicinal product is intended to be used for the preparation of medicated feed. **3.12 Withdrawal periods**

Pigs:

Meat and offal: 1 day.

4. <PHARMACOLOGICAL> <IMMUNOLOGICAL> INFORMATION

4.1 ATCvet code:

QA07AA92

4.2 Pharmacodynamics

As an aminoglycoside antibiotic apramycin binds to the 30S ribosomal subunit and interferes with the protein synthesis. Through mechanisms not yet completely elucidated, it acts on the cell wall and is bactericidal. The overall spectrum includes many aerobic or facultative anaerobic Gram-negative bacteria, including Enterobacteriaceae. It has no activity against anaerobic bacteria or under anaerobic conditions.
Susceptibility of the *E. coli* strains from pigs to apramycin can vary geographically and over time.
The most important mechanism of resistance against apramycin is the production of modifying enzymes that are usually encoded by resistance genes derived from plasmids. Depending on their spectrum, these enzymes may cause cross-resistance between aminoglycosides. Resistance may also be caused by a change of the ribosomal attachment sites, or the conveying system allowing the penetration of the cell.
Until harmonised international interpretative criteria relevant for susceptibility testing are available for apramycin, nationally approved and validated methods should be followed.

Resistance mechanisms: Different aminoglycoside 3-N acetyltransferase enzymes (AAC-3) have been related with resistance to apramycin. These enzymes confer different cross-resistance against other aminoglycosides. Apramycin resistance can be influenced by co-selection (resistance to apramycin has been described to be located in the same mobile genetic element that other resistant determinants in Enterobacteriaceae) and cross resistance (e. g. with gentamicin).

Resistance developed by chromosomal resistance is minimal for most of the aminoglycosides.

4.3 Pharmacokinetics

The oral administration of apramycin is intended for antimicrobial activity within the gut; apramycin is poorly absorbed, but absorption may be increased in young animals and in animals with disrupted intestinal barrier.
Apramycin is excreted in its active form via the kidney.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf-life after first opening the immediate packaging: 6 months.
Shelf life after incorporation into meal feed: 3 months.
Shelf life after incorporation into pelleted feed: 1 month.

5.3 Special precautions for storage

Veterinary medicinal product as packaged for sale: Do not store above 25°C. Store in the original package. Store in a dry place.
Veterinary medicinal product after first opening of the immediate packaging: Do not store above 25°C.
Medicated feed (mashed and pelleted): Do not store above 25°C.

5.4 Nature and composition of immediate packaging

Polyethylene-lined multiple-layer paper bags of 1 kg, 5 kg and 20 kg.
Not all pack sizes may be marketed.

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

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV

7. MARKETING AUTHORISATION NUMBER

Vm 30282/4019

8. DATE OF FIRST AUTHORISATION

14 August 2013

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

May 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Approved 01 September 2025

Gavin Hall