PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE {Paper bag}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
Apravet 100 g/kg premix for medicated feeding stuff

2. STATEMENT OF ACTIVE SUBSTANCES
Each kg contains:
Apramycin sulfate 100 g equivalent to apramycin 100.000.000 IU.

3. PACKAGE SIZE
1 kg, 5 kg or 20 kg.

4. TARGET SPECIES
Pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION
In feed use.

7. WITHDRAWAL PERIODS
Withdrawal period:
Pigs:

Meat and offal: 1 day.

8. EXPIRY DATE
Exp. {mm/yyyy}
Once opened, use within 6 months.
After incorporation into meal feed, use within 3 months.
After incorporation into pelleted feed, use within 1 month.

9. SPECIAL STORAGE PRECAUTIONS
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.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”
Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”
For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”
Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER
Huvepharma NV

14. MARKETING AUTHORISATION NUMBERS
Vm 30282/4019

15. BATCH NUMBER
Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product
Apravet 100 g/kg premix for medicated feeding stuff for pigs

2. Composition
Each kg contains:

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

Light brown granules.

3. Target species
Pigs.

4. Indications for use
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.

5. 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.

6. Special warnings
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.

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.

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.

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

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.

Overdose:
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.
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.

Special restrictions for use and special conditions for use:
This veterinary medicinal product is intended to be used for the preparation of medicated feed.

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

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

7. Adverse events

Pigs:

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 in this package leaflet, 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 using the contact details at the end of this leaflet, or via your national reporting system at:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

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.

9. Advice on correct administration

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.

To adjust dosing properly the following calculation can be used:

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

The intake of medicated feed depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of apramycin may need to be adjusted accordingly.Medicated feed may be pelleted using a pre-conditioning step for 5 minutes at a temperature not exceeding 85°C.

10. Withdrawal periods

Pigs:
Meat and offal: 1 day.

11. Special storage precautions

Keep out of the sight and reach of children.

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.

Do not use this veterinary medicinal product after the expiry date which is stated on the label

after Exp. The expiry date refers to the last day of that month.

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.

12. 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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 30282/4019
Polyethylene-lined multiple-layer paper bags of 1 kg, 5 kg and 20 kg.
Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]
Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Huvepharma NV
Uitbreidingstraat 80
2600 Antwerp
Belgium
+32 3 288 18 49
pharmacovigilance@huvepharma.com

Manufacturer responsible for batch release
Biovet JSC
39 Petar Rakov Str.
4550 Peshtera
Bulgaria

17. Other information

POM-V

Approved 01 September 2025
Gavin Hall