PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {PAPER BAG - NO SEPARATE OUTER PACKAGING, LABEL AND PACKAGE LEAFLET ARE ATTACHED TO THE BAG}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Apravet 100 000 IU/g premix for medicated feeding stuff

2. STATEMENT OF ACTIVE SUBSTANCES

Each g contains:

Active substance:
Apramycin 100 000 IU.
(as apramycin sulphate).

3. PACKAGE SIZE

1 kg, 5 kg or 20 kg.

4. TARGET SPECIES

Pigs and rabbits.

5. INDICATIONS

Read the package leaflet before use.

6. ROUTES OF ADMINISTRATION

In-feed.

7. WITHDRAWAL PERIODS

Withdrawal period:
Pigs: meat and offal - 21 days.
Rabbits: meat and offal - 1 day.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use by…

9. SPECIAL STORAGE PRECAUTIONS

Veterinary medicinal product as packaged for sale: Do not store above 25°C. Store in the original bag. Protect from moisture.
Veterinary medicinal product after first opening of the bag: Do not store above 25°C. Store in the original bag.

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.

To be supplied only on veterinary prescription.
Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.

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 N.V.

14. MARKETING AUTHORISATION NUMBER

Vm 30282/4026

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Apravet 100 000 IU/g premix for medicated feeding stuff for pigs and rabbits

2. Composition

Each g contains:

Active substance:
Apramycin 100 000 IU.
(as apramycin sulphate).

Excipients:
Starch, pregelatinised.
Wheat flour.

Light brown granules.

3. Target species

Pigs and rabbits.

4. Indications for use

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

Rabbits
Reduction in mortality and clinical signs related to epizootic enterocolitis due to *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 or any of the excipients.
Do not use in cats.

6. Special warnings

Special warnings for safe use in the target species:

The uptake of medication by animals can be altered as a consequence of illness. In case of insufficient uptake of feed animals alternative treatment should be considered, for example, by injection.
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 use in animals:

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 deviating from the instructions given in the SPC 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 or any other aminoglycoside should avoid contact with the veterinary medicinal product.
This veterinary medicinal product may cause irritation after skin or eye contact or inhalation. 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. Wear a protective 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) when mixing and handling the veterinary medicinal product.
In the event of eye contact, rinse the affected area with plenty of water. In the event of skin contact, wash thoroughly with soap and water. If irritation persists, seek medical advice. Wash hands after use. In the event of accidental ingestion, seek medical assistance immediately and show the package label to the physician. In case of onset of symptoms after exposure such as skin rash, seek medical advice immediately and show the package label to the physician. Swelling of the lips, face and eyes or difficulty breathing are more serious symptoms and require urgent medical assistance.

Pregnancy or lactation:

Laboratory studies in the rat and rabbit have not produced evidence of adverse effects in pregnant animals. The use is not recommended during the whole part of the pregnancy and in lactating animals.

Interaction with other medicinal products and other forms of interaction:

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.

In certain conditions with a high degree of humidity there might be an apparent interaction with lectins.

Overdose (symptoms, emergency procedures, antidotes):

No adverse effects were observed in pigs that were given up to nine times their recommended use level.

Major incompatibilities:

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

Environmental properties

Apramycin is very persistent in soils.

7. Adverse events

None known.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

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.

Pigs:
The dosage is of 4 000-8 000 IU/kg of bodyweight per day (equivalent to 4-8 g of the veterinary medicinal product per 100 kg of bodyweight per day).
Administer as the sole feeding stuff for at least 21 days.

Rabbits:
The dosage is of 12 000 IU/kg of bodyweight per day (equivalent to 12 g of the veterinary medicinal product per 100kg of bodyweight) for a period up to 21 days.

9. Advice on correct administration

For all species, the consumption of the medicated feed may depend of the clinical condition of the animals. In order to guarantee a correct dosing, the concentration of the veterinary medicinal product in the feed should be adjusted accordingly.

To ensure a correct dosage, bodyweight should be determined as accurately as possible.

To adjust dosing properly following calculation can be used:

… g product/kg b.w./day x average b.w. (kg) = … kg of the product/ton of feed
average daily feed intake (kg/animal)

Mixing Instructions:
It is recommended to initially mix the veterinary medicinal product with a small amount of the feeding stuff (20-50 kg) before incorporating it in the full amount of feeding stuff.
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 - 21 days
Rabbits: 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 bag. Protect from moisture.
Veterinary medicinal product after first opening of the bag: Do not store above 25°C. Store in the original bag. Keep the bag tightly closed in order to protect from light and moisture.
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.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

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 30282/4026

Polyethylene bag in a three-ply paper bag.

Pack sizes:
Bag of 1 kg.
Bag of 5 kg.
Bag of 20 kg.

Not all pack sizes may be marketed.

Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.

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 N.V.
Uitbreidingstraat 80
2600 Antwerp
Belgium
+32 3 288 18 49

Manufacturer responsible for batch release:

Biovet JSC
39 Petar Rakov Str.
4550 Peshtera
Bulgaria

17. Other information

POM-V

Gavin Hall

Approved: 16 July 2025