

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND IMMEDIATE PACKAGE { Carboard box of 25 or 50 sachets of 1,812g; bag of 1811,6g; bottle of 90,58 g }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Apravet 552 000 IU/g powder for use in drinking water/milk

2. STATEMENT OF ACTIVE SUBSTANCES

Each g contains :

Apramycin sulfate 552 IU

3. PACKAGE SIZE

90.58 g or 50 000 000 IU.
1811.6 g or 1 000 000 000 IU.
1.812 g or 1 000 000 IU.
25 x 1.812 g or 1 000 000 IU.
50 x 1.812 g or 1 000 000 IU.

4. TARGET SPECIES

Pigs (weaned piglet), cattle (pre-ruminant), chickens (broilers) and rabbits.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In drinking water/milk use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Pigs (weaned piglets):

-Meat and offal: Zero days.

Cattle (pre-ruminant):

-Meat and offal: 28 days.

Chickens (broilers):

-Meat and offal: Zero days.

-Not for use in birds producing eggs for human consumption. Do not use within 4 weeks of the start of the laying period.

Rabbits:

-Meat and offal: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Shelf life after first opening the container (bottle and bag): 28 days.

Shelf life after first opening the container (sachet): Use immediately.

Shelf life after dissolution in drinking water: 24 hours.

Shelf life after dissolution in milk replacer: use immediately.

(Bottle and bag) Once opened, use by:

9. SPECIAL STORAGE PRECAUTIONS

Store below 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 NUMBER

Vm 30282/4030

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Sachet of 1.812g}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Apravet 552 000 IU/g powder for use in drinking water/milk

2. STATEMENT OF ACTIVE SUBSTANCES

Each g contains :

Apramycin sulfate 552 IU

3. TARGET SPECIES

Pigs (weaned piglet), cattle (pre-ruminant), chickens (broilers) and rabbits.

4. ROUTES OF ADMINISTRATION

In drinking water/milk use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:

Pigs (weaned piglets):

-Meat and offal: Zero days.

Cattle (pre-ruminant):

-Meat and offal: 28 days.

Chickens (broilers):

-Meat and offal: Zero days.

- Not for use in birds producing eggs for human consumption. Do not use within 4 weeks of the start of the laying period.

Rabbits:

-Meat and offal: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}

Shelf life after first opening the container: use immediately

Shelf life after dissolution in drinking water: 24 hours.

Shelf life after dissolution in milk replacer: use immediately.

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Apravet 552 000 IU/g powder for use in drinking water/milk for pigs, calves, chickens and rabbits

2. Composition

Each g contains :

Active substance:
Apramycin sulfate 552 000 IU
(as apramycin sulphate).
Almost white to yellow powder.

3. Target species

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

4. Indications for use

Pigs (weaned piglets):
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.

Chickens (broilers):
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 veterinary medicinal product is used.

5. Contraindications

Do not use in cases of hypersensitivity to the active substance.
Do not use in cattle (pre-ruminant) with functional rumen.
Do not use in animals suffering from kidney disorders.

6. Special warnings

Special precautions for safe use in the target species:

Use of the veterinary medicinal product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

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.

Official, national and regional antimicrobial policies should be taken into account when the veterinary medicinal product is used.

User warnings:

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 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 veterinary medicinal 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.

Use during pregnancy, lactation or lay:

Pregnancy and lactation:

Pigs (weaned piglets):

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

Cattle (pre-ruminant):

The use is not intended during pregnancy or lactation.

Rabbits:

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:

Not for use in birds producing eggs for human consumption. Do not use within 4 weeks of the start of the laying period.

Interactions with other veterinary 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:

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

Cattle (pre-ruminant): 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.

Chickens (broilers): 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:

Incompatibilities:

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.

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

7. Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal 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

Route of administration:

In drinking water/milk use:

Drinking systems should be clean and free of rust to avoid reduction of activity. In the case of cattle (pre-ruminant) it can be administered in milk or milk replacer.

Dosing

Pigs (weaned piglets):

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

Cattle (pre-ruminant):

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

Chickens (broilers):

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

Rabbits:

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

9. Advice on correct administration

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:

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

To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid under-dosing. Prepare the solution with fresh tap water (or milk/milk replacer for calves) immediately before use. Milk replacer should be prepared prior to the addition of the powder. The solution should be vigorously stirred for 5 minutes. Medicated drinking water should be refreshed or replaced every 24 hours. Medicated milk/milk replacer should be consumed immediately after preparation. 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. If it is not possible to obtain sufficient uptake of medicated water, animals should be treated parenterally (where appropriate). The maximum solubility of the veterinary medicinal product in water and milk replacer is approximately 1000 g/L. The use of suitably calibrated measuring equipment is recommended.

10. Withdrawal periods

Pigs (weaned piglets):

-Meat and offal: Zero days.

Cattle (pre-ruminant):

-Meat and offal: 28 days.

Chickens (broilers):

-Meat and offal: Zero days.

- Not for use in birds producing eggs for human consumption. Do not use within 4 weeks of the start of the laying period.

Rabbits:

-Meat and offal: Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store below 25 °C

Do not use this veterinary medicinal product after 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 (bottle and bag): 28 days.

Shelf life after first opening the immediate packaging (sachet): use immediately.

Shelf life after dissolution in drinking water according to directions: 24 hours.

Shelf life after dissolution in milk replacer according to directions: use immediately.

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 NUMBER AND PACK SIZES

Vm 30282/4030

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.
Cardboard box containing 25 sachets of 1.812 g or 1 000 000 IU.
Cardboard box containing 50 sachets of 1.812 g or 1 000 000 IU.

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:

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerp
Belgium
+32 3 288 18 49

Manufacturer responsible for the batch release:

Biovet JSC
39 Petar Rakov Str,
4550 Peshtera
Bulgaria

17. Other information

POM-V

Approved 26 August 2025

Gavin Hall