

LABELLING

PARTICULARS TO APPEAR ON THE OUTER AND IMMEDIATE PACKAGE

Carboard box of 25 or 50 sachet of 1.812g; bag of 1811.6; bottle of 90.58 g

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Apramycin (as apramycin sulfate)

2. STATEMENT OF THE ACTIVE AND OTHER SUBSTANCES

Each mg contains :

Active substance:

Apramycin 552 IU*
(as apramycin sulfate)

*IU – international units

3. PHARMACEUTICAL FORM

Powder for use in drinking water/milk.

4. PACKAGE SIZE

90.58 g or 50 000 000 IU.

25 x 1.812 g or 1 000 000 IU.

50 x 1.812 g or 1 000 000 IU.

1811.6 g or 1 000 000 000 IU.

5. TARGET SPECIES

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

6. INDICATIONS

Read the package leaflet before use.

7. METHOD AND ROUTE OF ADMINISTRATION

In drinking water/milk use

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal periods:

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.

9. SPECIAL WARNING(S)

Read the package leaflet before use.

10. EXPIRY DATE

Exp <<EXP month/year>>

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 dilution in drinking water: 24 hours.

Shelf life after dilution in milk replacer: Use immediately. Do not store.

Once opened, use by:

11. SPECIAL STORAGE CONDITIONS

Store below 25°C

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerp
Belgium

16. MARKETING AUTHORISATION NUMBER

Vm 30282/4030

17. MANUFACTURER'S BATCH NUMBER

Batch <<number>>

7. EXPIRY DATE

Exp <<EXP month/year>>

Shelf life after first opening the immediate packaging: use immediately

Shelf life after dilution in drinking water: 24 hours.

Shelf life after dilution in milk replacer: Use immediately. Do not store.

FOR ANIMAL TREATMENT ONLY

PACKAGE LEAFLET

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.

5. CONTRAINDICATIONS

Do not administer in case of hypersensitivity to apramycin.

Do not use in calves with functional rumen.

Do not use in animals suffering from kidney disorders.

6. ADVERSE REACTIONS

None known.

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 inform your veterinary surgeon. Alternatively you can report via your national reporting system {national system details}'. For details regarding the national system please contact NCA.

7. TARGET SPECIES

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

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD(S) OF ADMINISTRATION

Route of 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.

Dosing

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.

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.

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

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

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 product in water and milk replacer is approximately 1000 g/L. The use of suitably calibrated weighing equipment is recommended to ensure accurate measurement of the amount of product to be administered.

10. WITHDRAWAL PERIODS

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.

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 the 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 dilution in drinking water: 24 hours.

Shelf life after dilution in milk replacer: Use immediately. Do not store.

12. SPECIAL WARNINGS

Special precautions for use in animals

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 product.

This 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 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

Pigs:

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:

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.

Chickens:

Do not use in laying hens and within 4 weeks before the onset of the laying period.

Interactions with other 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 (symptoms, emergency procedures, antidotes)

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

Calves: 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.

Chicken: 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.

Incompatibilities

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

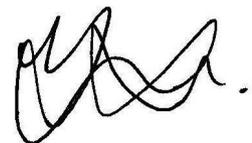
To be completed nationally

15. OTHER INFORMATION

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.



Approved: 24 January 2023