LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON OUTER PACKAGE AND THE IMMEDIATE PACKAGE

{Paper bag}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Apravet 100 g/kg premix for medicated feeding stuff for pigs
Apramycin sulphate

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each kg contains:
Apramycin sulfate 100 g, equivalent to apramycin 100.000.000 IU

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuff - Granular powder

4. PACKAGE SIZE

1 kg, 5 kg or 20 kg.

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: 1 day

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened, use by 6 months
After incorporation into meal feed, use by 3 months.
After incorporation into pelleted feed, use by 1 month

11. SPECIAL STORAGE CONDITIONS

Veterinary medicinal product as packaged for sale: Do not store above 25°C. Store in the original package. Protect from moisture.
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.

12. 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

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

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

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT 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 30282/4019

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Apravet 100 g/kg premix for medicated feeding stuff

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorization holder

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerp
Belgium

Manufacturer responsible for batch release

Biovet JSC
39 Petar Rakov Str.
4550 Peshtera
Bulgaria

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Apravet 100 g/kg premix for medicated feeding stuff for pigs
Apramycin sulphate

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each kg of light brown granules contains:

Active substance:
Apramycin sulfate 100 g, (corresponds to apramycin 100.000.000 IU)

4. INDICATION(S)

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

5. CONTRAINDICATIONS

Do not use in the cases of hypersensitivity to apramycin or any of the excipients.
Do not use in animals suffering from kidney disorders.
Do not use in cats

6. ADVERSE REACTIONS

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

7. TARGET SPECIES

Pigs

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

The dosage is 4 000-8 000 IU/kg of bodyweight per day (equivalent to 4-8 g of the 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 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 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 product in the feed should 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 PERIOD

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. Protect from moisture.
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 WARNING(S)

People with known hypersensitivity to apramycin should administer the product with care.
During preparation and administration of the medicated feedingstuff, skin, eye and oral contact with the 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 product.
Wash any contaminated skin. Wash hands carefully with soap and water after handling of the product. In the event of accidental ingestion, seek medical assistance immediately and show the package label.Laboratory studies have not produced evidence of teratogenic, foetotoxic or maternotoxic effects.
The use of is not recommended in pregnant or lactating sows.

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.

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.

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

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.
The use of the product should be combined with good management practices e.g. good hygiene, proper ventilation, no overstocking.

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

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.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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.

Approved 17 July 2018