ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

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 for pigs and rabbits

Apramycin

2. STATEMENT OF ACTIVE SUBSTANCES

Each g contains:

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

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuff. Light brown granules

4. PACKAGE SIZE

1 kg, 5 kg or 20 kg.

5. TARGET SPECIES

Pigs and rabbits

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

In feed use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Pigs: meat and offal - 21 days
Rabbits: 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…

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. Store in the original package.

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

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

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(S)

Vm 30282/4026

17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

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

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

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

Apramycin

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

Each g contains:

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

light brown granules

4. INDICATION(S)

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.*

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. 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 and rabbits.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 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 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 product in the feed should be adjusted accordingly.

To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid under-dosing.

To adjust dosing properly following calculation can be used:

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

Mixing Instructions:
It is recommended to initially mix the 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 PERIOD

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 package. Protect from moisture.
Veterinary medicinal product after first opening of the immediate packaging: Do not store above 25°C. Store in the original package.
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)

Special warnings for each 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 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 product should be based on susceptibility testing. Official, national and regional antimicrobial policies should be taken into account when the veterinary medicinal product is used.
Use of the 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 product.
This 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 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.
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. However, the use of the product is not recommended in pregnant or lactating animals.

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.

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

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

September 2021

15. OTHER INFORMATION

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.

Approved 08 October 2021