ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

Outer carton + label for 1 bottle of 125 ml
Outer carton + label for 1 bottle of 250 ml
Outer carton + label for 1 bottle of 500 ml
Outer carton + label for 1 bottle of 1 L

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gabbrovet 140 mg/ml solution for use in drinking water / milk or milk replacer for pre-ruminant cattle and pigs

Paromomycin as sulfate

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains140 mg of paromomycin (as sulfate), equivalent to 140,000 IU of paromomycin activity or equivalent to approximately 200 mg of paromomycin sulfate.

3. PHARMACEUTICAL FORM

Solution for use in drinking water, milk or milk replacer.
Pale yellow to yellow solution.

4. PACKAGE SIZE

125 ml
250 ml
500 ml
1 L

5. TARGET SPECIES

Cattle (pre-ruminant cattle) and pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle: Meat and offal: 20 days

Pigs: Meat and offal: 3 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:
Once opened, use within 6 months by __/__/__. Once reconstituted in drinking water, use within 24 hours. Once reconstituted in milk or milk replacer, use within 6 hours.

11. SPECIAL STORAGE CONDITIONS

After first opening, keep the bottle tightly closed.
For 125 ml and 250 ml:
Do not store above 25° C.

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

Not required on the immediate label
Disposal: read package leaflet.

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

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 15052/3002

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle of 125 ml
Bottle of 250 ml
Bottle of 500 ml
Bottle of 1 L
[Label with no outer carton nor package leaflet]

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gabbrovet 140 mg/ml solution for use in drinking water / milk or milk replacer for pre-ruminant cattle and pigs
Paromomycin as sulfate

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Active substance: 140 mg of paromomycin (as sulfate), equivalent to 140,000 IU of paromomycin activity or equivalent to approximately 200 mg of paromomycin sulfate.
Excipients; 7.5 mg of benzyl alcohol (E1519) and 3.0 mg of sodium metabisulfite (E223).

3. PHARMACEUTICAL FORM

Solution for use in drinking water, milk or milk replacer.
Pale yellow to yellow solution.

4. PACKAGE SIZE

125 ml
250 ml
500 ml
1 L

5. TARGET SPECIES

Cattle (pre-ruminant cattle) and pigs

6. INDICATIONS AND CONTRAINDICATIONS

6.1 Indications

Treatment of gastro-intestinal infections caused by *Escherichia coli* susceptible to paromomycin.

6.2 Contraindications

Do not use in animals with known hypersensitivity to paromomycin, other aminoglycosides or any of the excipients.
Do not use in cases with impaired function of the kidneys or liver.
Do not use in ruminating animals.

Do not use in turkeys due to the risk of selection for antimicrobial resistance in intestinal bacteria.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Duration of treatment: 3-5 days.
Pre-ruminant cattle: administration in milk/milk replacer: 1.25 - 2.5 ml of product/10 kg BW/day, equivalent to 17500 - 35000 IU of paromomycin per kg BW/day (i.e. approximately 25-50 mg paromomycin sulfate per kg BW/day).
Pigs: administration in drinking water: 1.25 - 2 ml of product/10 kg BW/day, equivalent to 17500 - 28000 IU of paromomycin per kg BW/day (i.e. approximately 25-40 mg paromomycin sulfate per kg BW/day).
For the administration through the drinking water, the exact daily amount of product should be based on the number of animals to be treated and the recommended dose calculated according to the following formula:

$$\frac{\text{ml product/ kg BW/day} \times \text{Mean bodyweight (kg) of animals to be treated}}{\text{Mean daily water consumption (litre) per animal}} = \text{ml product per litre drinking water/day/animal}$$

To ensure a correct dosage bodyweight should be determined as accurately as possible.
The uptake of medicated water depends on several factors including clinical conditions of the animals and the local conditions such as ambient temperature and humidity. In order to obtain the correct dosage, uptake of drinking water has to be monitored and the concentration of paromomycin has to be adjusted accordingly.
Medicated drinking water/milk/milk replacer and any stock solutions should be freshly prepared every 6 hours (in milk/milk replacer) or every 24 hours (in water).

8. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle: Meat and offal: 20 days
Pigs: Meat and offal: 3 days

9. SPECIAL WARNING(S), IF NECESSARY

Special warnings for each target species
None.

Special precautions for use in animals
The uptake of medication by animals can be altered as a consequence of illness. In case of insufficient uptake of water/milk animals should be treated parenterally using a suitable injectable product following the advice of the veterinarian.
The use of the product should be combined with good management practices e.g. good hygiene, proper ventilation, no overstocking.

Since the product is potentially ototoxic and nephrotoxic, it is recommended to assess kidney function. Special care should be taken when considering administration of the product to newborn animals due to the known higher gastrointestinal absorption of paromomycin in neonates. This higher absorption could lead to an increased risk of oto-and nephrotoxicity. The use of the product in neonates should be based on benefit-risk assessment by the responsible veterinarian.
Prolonged or repeated use of the product should be avoided by improving management practices and through cleansing and disinfection. Use of the 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 product is used.
Use of the product deviating from the given instructions may increase the prevalence of bacteria resistant to paromomycin and may decrease the effectiveness of treatment with aminoglycosides due to the potential for cross-resistance.
Aminoglycosides are considered as critical in human medicine. Consequently, they should not be used as a first intention treatment in veterinary medicine.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

- This product contains paromomycin, which can cause allergic reactions in some people.
- People with known hypersensitivity (allergy) to paromomycin or any other aminoglycosides should avoid contact with the product.
- Avoid contact with the skin and eyes.
- Personal protective equipment consisting of protective clothing and impervious gloves should be worn when handling the product.
- In the event of accidental contact with the skin or eyes, rinse with plenty of water.
- If you develop symptoms following exposure, such as skin rash, you should seek medical advice and show the physician this warning. Swelling of the face, lips and eyes or difficulty in breathing are more serious symptoms and require urgent medical attention.
- Do not eat, drink and smoke when handling the product.
- Do not ingest. In case of accidental ingestion, seek medical advice immediately and show the label to the physician.
- Wash hands after use.

Adverse reactions

In rare occasions soft faeces has been observed.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

Aminoglycoside antibiotics such as paromomycin can cause oto- and nephrotoxicity.
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. For details regarding the national system please contact NCA.

Pregnancy and lactation
Laboratory studies in the rat and rabbit have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects. The use is not recommended during pregnancy.

Interaction
General anaesthetics and muscle relaxing products increase the neuro-blocking effect of aminoglycosides. This may cause paralysis and apnoea.
Do not use concurrently with strong diuretics and potentially oto- or nephrotoxic substances.

Overdose (symptoms, emergency procedures, antidotes)
Paromomycin when administered orally is hardly absorbed systemically. Harmful effects due to accidental overdosing are highly unlikely.

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

10. EXPIRY DATE

EXP:
Once opened, use within 6 months by __/__/__. Once reconstituted in drinking water, use within 24 hours. Once reconstituted in milk or milk replacer, use within 6 hours.
Do not use this veterinary medicinal product after the expiry date stated on the container after "EXP". The expiry date refers to the last day of that month.

11. SPECIAL STORAGE CONDITIONS

After first opening, keep the bottle tightly closed.
For 125 ml and 250 ml:
Do not store above 25° C.
For 500 ml and 1 L:
This veterinary medicinal product does not require any special storage conditions.

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. 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

Marketing authorisation holder:
Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

Manufacturer responsible for batch release:
Ceva Santé Animale, Z.I. Très le Bois, 22600 Loudéac, France

16. MARKETING AUTHORISATION NUMBER

Vm 15052/3002

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

Other information
Pack sizes:
Box containing 1 plastic bottle of 125 ml,
Box containing 1 plastic bottle of 250 ml
Box containing 1 plastic bottle of 500 ml
Box containing 1 plastic bottle of 1 L
125 ml plastic bottle
250 ml plastic bottle
500 ml plastic bottle
1-Litre plastic bottle
For each listed pack size, a dosing device is joined.
Not all pack sizes may be marketed.

Date on which the package leaflet was last approved:
{month/year}

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Gabbrovet 140 mg/ml solution for use in drinking water / milk or milk replacer for pre-ruminant cattle and pigs

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

Marketing authorisation holder:
Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

Manufacturer responsible for batch release:
Ceva Santé Animale, Z.I. Très le Bois, 22600 Loudéac, France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gabbrovet 140 mg/ml solution for use in drinking water / milk or milk replacer for pre-ruminant cattle and pigs
Paromomycin as sulfate

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

Each ml contains:
Active substance: 140 mg of paromomycin (as sulfate), equivalent to 140,000 IU of paromomycin activity or equivalent to approximately 200 mg of paromomycin sulfate.
Excipients: 7.5 mg of benzyl alcohol (E1519) and 3.0 mg of sodium metabisulfite (E223).
Pale yellow to yellow solution.

4. INDICATION(S)

Treatment of gastro-intestinal infections caused by *Escherichia coli* susceptible to paromomycin.

5. CONTRAINDICATIONS

Do not use in animals with known hypersensitivity to paromomycin, other aminoglycosides or any of the excipients.
Do not use in cases with impaired function of the kidneys or liver.
Do not use in ruminating animals.
Do not use in turkeys due to the risk of selection for antimicrobial resistance in intestinal bacteria.

6. ADVERSE REACTIONS

In rare occasions soft faeces has been observed.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

Aminoglycoside antibiotics such as paromomycin can cause oto- and nephrotoxicity.
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. For details regarding the national system please contact NCA.

7. TARGET SPECIES

Cattle (pre-ruminant cattle) and pigs

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

Oral use.
Duration of treatment: 3-5 days.
Pre-ruminant cattle: administration in milk/milk replacer: 1.25 - 2.5 ml of product/10 kg BW/day, equivalent to 17500 - 35000 IU of paromomycin per kg BW/day (i.e. approximately 25-50 mg paromomycin sulfate per kg BW/day).
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$$\frac{\text{ml product/ kg BW/day} \times \text{Mean bodyweight (kg) of animals to be treated}}{\text{Mean daily water consumption (litre) per animal}} = \text{ml product per litre drinking water/day/animal}$$

To ensure a correct dosage bodyweight should be determined as accurately as possible.
The uptake of medicated water depends on several factors including clinical conditions of the animals and the local conditions such as ambient temperature and humidity. In order to obtain the correct dosage, uptake of drinking water has to be monitored and the concentration of paromomycin has to be adjusted accordingly.

Medicated drinking water/milk/milk replacer and any stock solutions should be freshly prepared every 6 hours (in milk/milk replacer) or every 24 hours (in water).

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIODS

Cattle: Meat and offal: 20 days
Pigs: Meat and offal: 3 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
125 ml and 250 ml: Do not store above 25° C.
500 ml and 1 L: This veterinary medicinal product does not require any special storage conditions.
All presentations: After first opening, keep the bottle tightly closed.
Shelf life after first opening the immediate packaging: 6 months.
Shelf life after reconstitution in drinking water: 24 hours.
Shelf life after reconstitution in milk or milk replacer: 6 hours.
Do not use this veterinary medicinal product after the expiry date which is stated on the container after "EXP". The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species
None.

Special precautions for use in animals
The uptake of medication by animals can be altered as a consequence of illness. In case of insufficient uptake of water/milk animals should be treated parenterally using a suitable injectable product following the advice of the veterinarian.
The use of the product should be combined with good management practices e.g. good hygiene, proper ventilation, no overstocking.
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- If you develop symptoms following exposure, such as skin rash, you should seek medical advice and show the physician this warning. Swelling of the face, lips and eyes or difficulty in breathing are more serious symptoms and require urgent medical attention.
- Do not eat, drink and smoke when handling the product.
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Laboratory studies in the rat and rabbit have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects. The use is not recommended during pregnancy.

Interaction

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Do not use concurrently with strong diuretics and potentially oto- or nephrotoxic substances.

Overdose (symptoms, emergency procedures, antidotes)

Paromomycin when administered orally is hardly absorbed systemically. Harmful effects due to accidental overdosing are highly unlikely.

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 PRODUCT 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

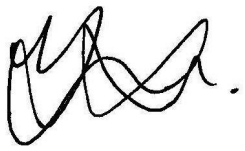
December 2022

15. OTHER INFORMATION

Other information

Pack sizes:

Box containing 1 plastic bottle of 125 ml,
Box containing 1 plastic bottle of 250 ml
Box containing 1 plastic bottle of 500 ml
Box containing 1 plastic bottle of 1 L
125 ml plastic bottle
250 ml plastic bottle
500 ml plastic bottle
1-Litre plastic bottle
For each listed pack size, a dosing device is joined.
Not all pack sizes may be marketed.



Approved: 02 May 2023