LABELLING AND PACKAGE LEAFLET

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle of 250 ml, 500 ml or 1 L

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Halofusol 0.5 mg/ml oral solution for calves
Halofuginone

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:
Halofuginone 0.50 mg
Equivalent to 0.6086 mg of halofuginone lactate

Excipients:
Benzoic acid (E 210) 1.00 mg
Tartrazine (E 102) 0.03 mg

3. PHARMACEUTICAL FORM

Oral solution

4. PACKAGE SIZE

250 ml
500 ml
1000 ml

5. TARGET SPECIES

Cattle (newborn calves).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Meat and offal: 13 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened use within 6 months
Use by:

11. SPECIAL STORAGE CONDITIONS

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

Disposal: read the 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

LABORATORIOS KARIZOO, S.A.
Pol. Ind. La Borda, Mas Pujades 11-12
08140 Caldes de Montbui
Spain

16. MARKETING AUTHORISATION NUMBER(S)

Vm 31223/4009

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton of 1x250 ml
Carton of 1x500 ml
Carton of 1x1000 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Halofusol 0.5 mg/ml oral solution for calves
Halofuginone

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active substance:
Halofuginone 0.50 mg
Equivalent to 0.6086 mg of halofuginone lactate

Excipients:
Benzoic acid (E 210) 1.00 mg
Tartrazine (E 102) 0.03 mg

3. PHARMACEUTICAL FORM

Oral solution.

4. PACKAGE SIZE

250 ml
500 ml
1000 ml

5. TARGET SPECIES

Cattle (newborn calves).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Meat and offal: 13 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened use within 6 months
Use by:

11. SPECIAL STORAGE CONDITIONS

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

Disposal: read the 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

LABORATORIOS KARIZOO, S.A.
Pol. Ind. La Borda, Mas Pujades 11-12
08140 Caldes de Montbui
Spain

16. MARKETING AUTHORISATION NUMBER(S)

Vm 31223/4009

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PACKAGE LEAFLET

PACKAGE LEAFLET:
Halofusol **0.5 mg/ml oral solution for calves**

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

Marketing authorisation holder and manufacturer responsible for batch release:
LABORATORIOS KARIZOO, S.A.
Polígono Industrial La Borda
Mas Pujades, 11-12
08140 – CALDES DE MONTBUI (Barcelona)
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Halofusol 0.5 mg/ml oral solution for calves
Halofuginone (as lactate salt)

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

Each ml contains:

Active substance:
Halofuginone 0.50 mg
Equivalent to 0.6086 mg of halofuginone lactate

Excipients:
Benzoic acid (E 210) 1.00 mg
Tartrazine (E 102) 0.03 mg

Clear yellow oral solution.

4. INDICATION(S)

In new born calves:

- Prevention of diarrhoea due to diagnosed *Cryptosporidium parvum* in farms with history of cryptosporidiosis.
  Administration should start in the first 24 to 48 hours of life.
- Reduction of diarrhoea due to diagnosed *Cryptosporidium parvum*.
  Administration should start within 24 hours after the onset of diarrhoea.

In both cases, the reduction of oocysts excretion has been demonstrated.

5. CONTRAINDICATIONS

Do not use on an empty stomach.
Do not use in cases of diarrhoea established for more than 24 hours and in weak animals.
Do not use in known cases of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

In very rare cases, an increase in the level of diarrhoea has been observed in treated animals.

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).

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}.

7. TARGET SPECIES

Cattle (newborn calves).

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

For oral use in calves after feeding.

The dosage is: 100 µg of halofuginone base / kg bw / once a day for 7 consecutive days, i.e. 4 ml of the product / 20 kg bw / once a day for 7 consecutive days.

However, in order to make the product treatment easier, a simplified dosage scheme is proposed:

- 35 kg < calves ≤ 45 kg: 8 ml of the product once a day during 7 consecutive days
- 45 kg < calves < 60 kg: 12 ml of the product once a day during 7 consecutive days

For smaller or higher weights, a precise calculation should be performed (4 ml/20 kg). To ensure a correct dosage, the use of either the metering pump included or any appropriate device for oral administration is necessary.

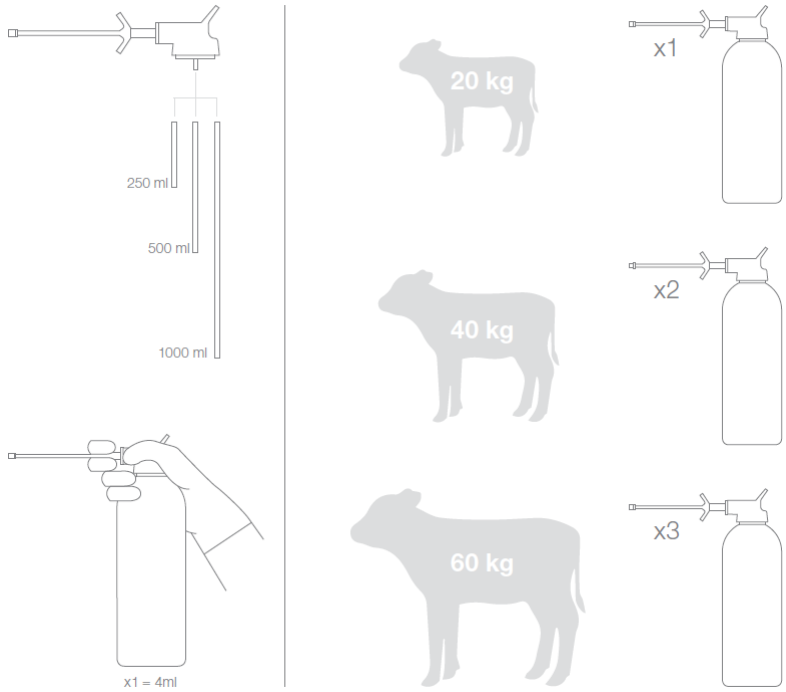
The consecutive treatment should be done at the same time each day.

Once the first calf has been treated, all the forthcoming new-born calves must be systematically treated as long as the risk for diarrhoea due to *C. parvum* persists.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure a correct dosage, the use of either the metering pump included or any appropriate device for oral administration is necessary. In case of using the metering pump included, it should not be used upside down, and has to be proceed as follows:

1) Screw the metering pump on the bottle.
2) Remove the protector cap from the nozzle.
3) If the metering pump is used for the first time (or hasn't been used for a few days), carefully pump till a drop of solution is formed on top of the nozzle.
4) Restrain the calf and insert the nozzle of the metering pump into the calves mouth.
5) Pull the trigger of the metering pump completely for release of a dose that equals 4 ml of solution. Pull twice or three times, respectively, for administration of the desired volume (8 ml for calves of 35 – 45 kg and 12 ml for calves of 45 – 60 kg, respectively).
6) Unscrew the metering pump on the bottle.
7) Close the bottle with the screw cap.
8) Pull twice or three times in order to empty the remained product in the metering pump.
9) Put the protector cap back on the nozzle.



10. WITHDRAWAL PERIOD(S)

Meat and offal: 13 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening the container: 6 months.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
Administer after colostrum feeding, or after milk or milk replacer feeding only, using either the metering pump included or any appropriate device for oral administration. Do not use on an empty stomach. For treatment of anorexic calves, the product should be administered in half a litre of an electrolyte solution. The animals should receive enough colostrum according to good breeding practice.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to the active substance or any of the excipients should administer the veterinary medicinal product with caution.
Repetitive contact with the product may lead to skin allergies.
Avoid skin and eye contact with the product. In case of skin and eye contact wash the exposed area thoroughly with clean water. If an eye irritation persists, seek medical advice.
Wear protective gloves while handling the product.
Wash hands after use.

Overdose (symptoms, emergency procedures, antidotes):
As symptoms of toxicity may occur at twice the therapeutic dose, it is necessary to apply the recommended dosage strictly. Symptoms of toxicity include diarrhoea, visible blood in faeces, decline in milk consumption, dehydration, apathy and prostration. Should clinical signs of overdosing occur the treatment must be stopped immediately and the animal fed unmedicated milk or milk replacer. Rehydration may be necessary.

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

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.
The product should not enter water courses as this may be dangerous for fish and other aquatic organisms.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Package sizes:
Bottle of 250 ml
Cardboard box containing 1 bottle of 250 ml with a 4 ml metering pump
Cardboard box containing 1 bottle of 250 ml
Bottle of 500 ml
Cardboard box containing 1 bottle of 500 ml with a 4 ml metering pump
Cardboard box containing 1 bottle of 500 ml
Bottle of 1000 ml
Cardboard box containing 1 bottle of 1000 ml with a 4 ml metering pump
Cardboard box containing 1 bottle of 1000 ml

Not all packs sizes may be marketed.

To be supplied only on veterinary prescription.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

Bottle of 250 ml, 500 ml or 1 L

1. Name and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release , if different

Marketing authorisation holder and manufacturer responsible for batch release:

LABORATORIOS KARIZOO, S.A.
Polígono Industrial La Borda
Mas Pujades, 11-12
08140 – CALDES DE MONTBUI (Barcelona)
Spain

2. Name of the veterinary medicinal product

Halofusol 0.5 mg/ml oral solution for calves
Halofuginone (as lactate salt)

3. Statement of the active substance (s) and other ingredients

Each ml contains:

Active substance:
Halofuginone 0.50 mg
Equivalent to 0.6086 mg of halofuginone lactate

Excipients:
Benzoic acid (E 210) 1.00 mg
Tartrazine (E 102) 0.03 mg

Clear yellow oral solution.

4. Pharmaceutical form

Oral Solution

5. Package size

250 ml
500 ml
1000 ml

6. Indication(s)

In new born calves:

- Prevention of diarrhoea due to diagnosed *Cryptosporidium parvum* in farms with history of cryptosporidiosis.
  Administration should start in the first 24 to 48 hours of life.
- Reduction of diarrhoea due to diagnosed *Cryptosporidium parvum*.
  Administration should start within 24 hours after the onset of diarrhoea.

In both cases, the reduction of oocysts excretion has been demonstrated.

7. Contraindications

Do not use on an empty stomach.
Do not use in cases of diarrhoea established for more than 24 hours and in weak animals.
Do not use in known cases of hypersensitivity to the active substance or to any of the excipients.

8. Adverse reactions

In very rare cases, an increase in the level of diarrhoea has been observed in treated animals.

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).

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}.

9. Target species

Cattle (newborn calves).

10. Dosage for each species, route(s) and method of administration

For oral use in calves after feeding.

The dosage is: 100 µg of halofuginone base / kg bw / once a day for 7 consecutive days, i.e. 4 ml of the product / 20 kg bw / once a day for 7 consecutive days.

However, in order to make the product treatment easier, a simplified dosage scheme is proposed:

• 35 kg < calves ≤ 45 kg: 8 ml of the product once a day during 7 consecutive days
• 45 kg < calves < 60 kg: 12 ml of the product once a day during 7 consecutive days

For smaller or higher weights, a precise calculation should be performed (4 ml/20 kg). To ensure a correct dosage, the use of either the metering pump included or any appropriate device for oral administration is necessary.

The consecutive treatment should be done at the same time each day.

Once the first calf has been treated, all the forthcoming new-born calves must be systematically treated as long as the risk for diarrhoea due to *C. parvum* persists.

11. Advice on correct administration

To ensure a correct dosage, the use of either the metering pump included or any appropriate device for oral administration is necessary. In case of using the metering pump included, it should not be used upside down, and has to be proceed as follows:

1) Screw the metering pump on the bottle.
2) Remove the protector cap from the nozzle.
3) If the metering pump is used for the first time (or hasn't been used for a few days), carefully pump till a drop of solution is formed on top of the nozzle.
4) Restrain the calf and insert the nozzle of the metering pump into the calves mouth.
5) Pull the trigger of the metering pump completely for release of a dose that equals 4 ml of solution. Pull twice or three times, respectively, for administration of the desired volume (8 ml for calves of 35 – 45 kg and 12 ml for calves of 45 – 60 kg, respectively).
6) Unscrew the metering pump on the bottle.
7) Close the bottle with the screw cap.
8) Pull twice or three times in order to empty the remained product in the metering pump.
9) Put the protector cap back on the nozzle.

12. Withdrawal period(s)

Withdrawal period(s):

Meat and offal: 13 days

13. Special storage precautions

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening the container: 6 months.

14. Special warning(s)

Special precautions for use in animals:
Administer after colostrum feeding, or after milk or milk replacer feeding only, using either the metering pump included or any appropriate device for oral administration. Do not use on an empty stomach. For treatment of anorexic calves, the product should be administered in half a litre of an electrolyte solution. The animals should receive enough colostrum according to good breeding practice.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to the active substance or any of the excipients should administer the veterinary medicinal product with caution.
Repetitive contact with the product may lead to skin allergies.
Avoid skin and eye contact with the product. In case of skin and eye contact wash the exposed area thoroughly with clean water. If an eye irritation persists, seek medical advice.
Wear protective gloves while handling the product.
Wash hands after use.

Overdose (symptoms, emergency procedures, antidotes):
As symptoms of toxicity may occur at twice the therapeutic dose, it is necessary to apply the recommended dosage strictly. Symptoms of toxicity include diarrhoea, visible blood in faeces, decline in milk consumption, dehydration, apathy and prostration. Should clinical signs of overdosing occur the treatment must be stopped immediately and the animal fed unmedicated milk or milk replacer. Rehydration may be necessary.

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

15. Special precautions for the disposal of unused product or waste materials, if any

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.
The product should not enter water courses as this may be dangerous for fish and other aquatic organisms.

16. Date on which the label was last approved

17. Other information

Package sizes:
Bottle of 250 ml
Cardboard box containing 1 bottle of 250 ml with a 4 ml metering pump
Cardboard box containing 1 bottle of 250 ml
Bottle of 500 ml

Cardboard box containing 1 bottle of 500 ml with a 4 ml metering pump
Cardboard box containing 1 bottle of 500 ml
Bottle of 1000 ml
Cardboard box containing 1 bottle of 1000 ml with a 4 ml metering pump
Cardboard box containing 1 bottle of 1000 ml

Not all packs sizes may be marketed.

To be supplied only on veterinary prescription.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

18. 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.

19. The words "Keep out of the sight and reach of children"

Keep out of the sight and reach of children.

20. Expiry date

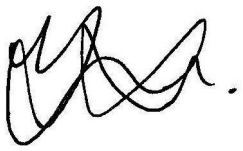
EXP {month/year}
Once opened use within 6 months
Use by:

21. Marketing authorisation number(s)

Vm 31223/4009

22. Manufacturer's batch number

Batch {number}



Approved: 23 December 2020