ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

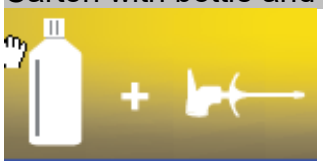
Outer carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Kriptazen 0.5 mg/ml oral solution for calves
halofuginone

Carton with bottle only
Refill

Carton with bottle and dosing device



2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active substance:

halofuginone (as lactate salt)	0.50 mg

3. PHARMACEUTICAL FORM

Oral solution.

4. PACKAGE SIZE

490 ml
980 ml

5. TARGET SPECIES

Cattle (newborn calves).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use in calves after feeding.

Package without a metering pump:
To ensure a correct dosage, the use of either a syringe or any appropriate device for oral administration is necessary.

Package with a metering pump:
In cases where the dosing pump is unsuitable for the weight of animals to be treated, either a syringe or any other appropriate device can be used.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods: 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.
Once broached, use by …

11. SPECIAL STORAGE CONDITIONS

Keep the bottle in the outer carton in order to protect from light.
Store upright in the original packaging.

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

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

VIRBAC
1ère avenue – 2065 m – LID
06516 Carros
France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 05653/5012

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle of 490 ml or 980 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Kriptazen 0.5 mg/ml oral solution for calves
halofuginone

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance:
Halofuginone (as lactate salt) 0.5 mg/ml

3. PHARMACEUTICAL FORM

Oral solution.

4. PACKAGE SIZE

490 ml
980 ml

5. TARGET SPECIES

Cattle (newborn calves).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods: 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.

11. SPECIAL STORAGE CONDITIONS

Keep the bottle in the outer carton in order to protect from light.
Store upright in the original packaging.

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

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"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue – 2065 m – LID
06516 Carros
France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 05653/5012

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Kriptazen 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:

VIRBAC
1ère avenue – 2065 m – LID
06516 Carros
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Kriptazen 0.5 mg/ml oral solution for calves
halofuginone

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

Each ml contains:
Active substance:

Halofuginone (as lactate salt)	0.50 mg

Excipients:

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

Clear yellow solution.

4. INDICATION(S)

Cattle (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 age.
- 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 cases of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

An increase in the level of diarrhoea has been observed in rare cases 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 reactions)
- 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.

7. TARGET SPECIES

Cattle (new born 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 / kg bw, once a day for 7 consecutive days; i.e. 2 ml of Kriptazen / 10 kg bw, once a day for 7 consecutive days.

The consecutive treatment should be administered 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

[Bottle without a pump:] To ensure a correct dosage, the use of either a syringe or any appropriate device for oral administration is necessary.

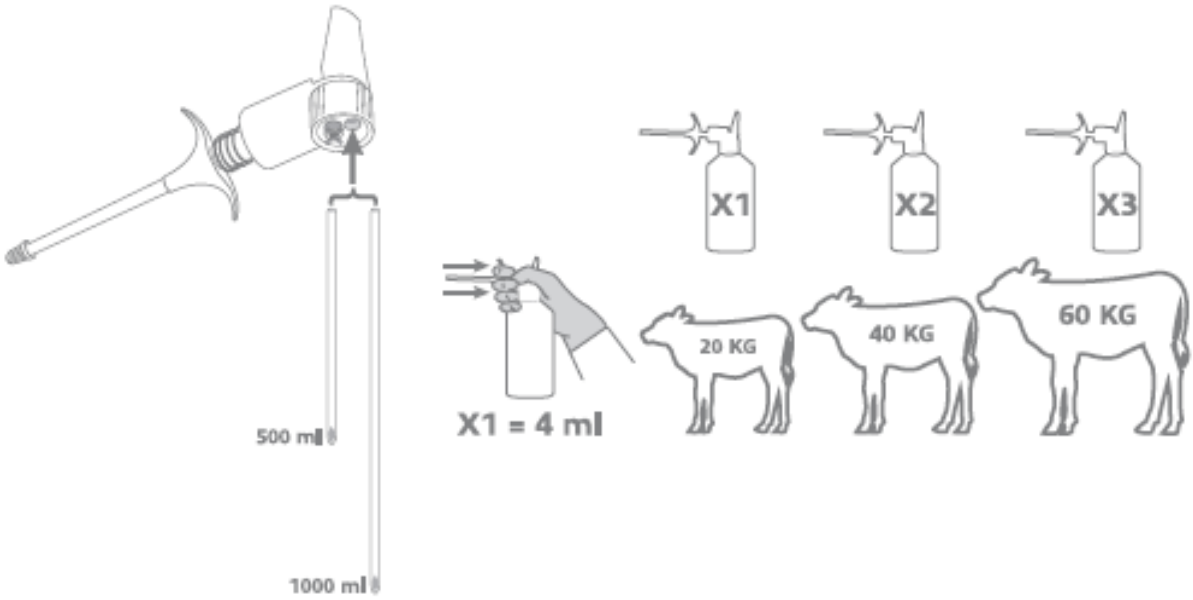
[Bottle with a 4 ml pump:] To ensure a correct dosage, the most appropriate metering pump should be selected, depending on the weight of the animals to be treated. In

cases where the dosing pump is unsuitable for the weight of animals to be treated, either a syringe or any other appropriate device can be used.

4 ml pump

1) Choose the dip tube designed for the height of the bottle (the shorter one for the 490 ml bottle and the longer one for the 980 ml) and insert it into the free hole located in the base of the pump cap.
2) Remove the cap and the protective seal from the bottle and screw the pump on.

3) Remove the protector cap from the tip of the nozzle of the pump.
4) Prime the pump by pressing the trigger gently, until a drop appears at the tip of the nozzle.
5) Restrain the calf and insert the nozzle of the metering pump into its mouth
6) Pull the trigger of the metering pump completely for release of a dose that equals 4 ml of solution. Pull two or three times, respectively, for administration of the desired volume (8 ml for calves weighing more than 35 kg but less than or equal to 45 kg and 12 ml for calves weighing more than 45 kg but less than or equal to 60 kg, respectively). For lighter or heavier animal weights, a precise calculation should be performed (2 ml/10 kg bw).
7) Continue using until the bottle is empty. If product remains in the bottle, leave the pump attached until further use.
8) Always replace the cap on the tip of the nozzle after use.
9) Always replace the bottle in the box.



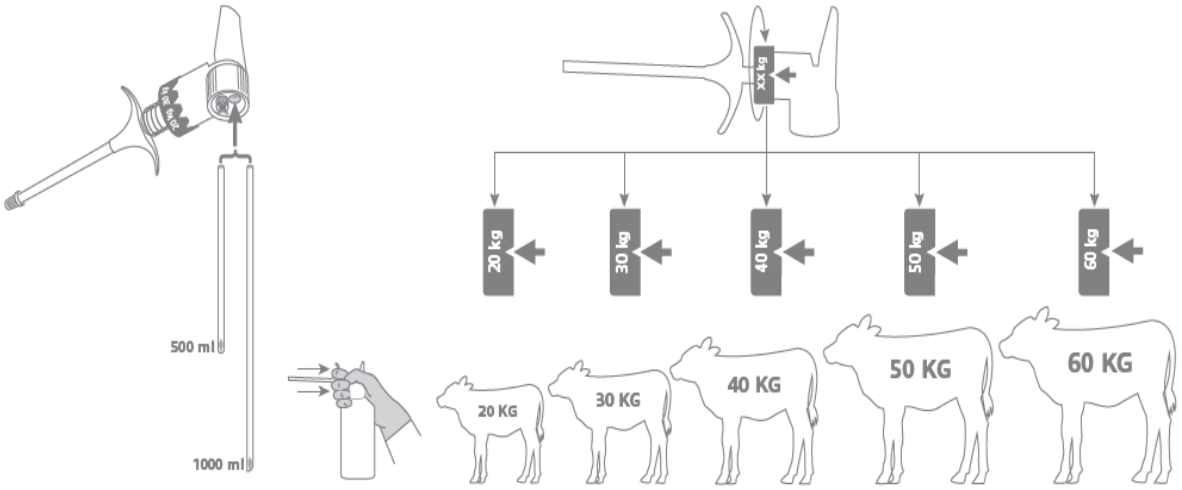
[Bottle with a 4 to 12 ml pump:] To ensure a correct dosage, the most appropriate metering pump should be selected, depending on the weight of the animals to be

treated. In cases where the dosing pump is unsuitable for the weight of animals to be treated, either a syringe or any other appropriate device can be used.

4 to 12 ml pump

1) Choose the dip tube designed for the height of the bottle (the shorter one for the 490 ml bottle and the longer one for the 980 ml) and insert it into the free hole located in the base of the pump cap.
2) Remove the cap and the protective seal from the bottle and screw the pump on.

3) Remove the protector cap from the tip of the nozzle of the pump.
4) To prime the pump, turn the dosage ring and select 60 kg (12 ml).
5) Press the trigger gradually with the cannula pointed up, until a drop appears at the tip of the nozzle.
6) Turn the ring, in order to select the weight of the calf to be treated.
7) Restrain the calf and insert the nozzle of the metering pump into its mouth.
8) Pull the trigger of the metering pump completely for release of the adequate dose.
9) Continue using until the bottle is empty. If product remains in the bottle, leave the pump attached until further use.
10) Always replace the cap on the tip of the nozzle after use.
11) Always replace the bottle in the box.



NOTE: The package leaflet on the market shall mention either the 4 ml pump or the 4 to 12 ml pump or the refill bottle without a pump as appropriate.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 13 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Keep the bottle in the outer carton in order to protect from light.
Store upright in the original packaging.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.

Shelf-life after first opening the immediate packaging: 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 an 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, eye or mucosal contact with the product.
- Wear protective gloves while handling the product.
- In case of skin and eye contact wash the exposed area thoroughly with clean water. If eye irritation persists, seek medical advice.
- 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.

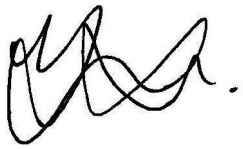
The product should not enter watercourses as this may be dangerous for fish and other aquatic organisms.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Cardboard box with a 500 ml bottle containing 490 ml or a 1000 ml bottle containing 980 ml, with or without a dosing pump.
Not all pack sizes may be marketed.

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



Approved: 18 August 2023