

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Kriptazen 0.5 mg/ml oral solution for calves

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Halofuginone 0.50 mg
(as lactate salt)

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Benzoic acid (E 210)	1.00 mg
Tartrazine (E 102)	0.03 mg
Lactic acid (E 270)	
Water, Purified	

Clear yellow solution.

3. CLINICAL INFORMATION

3.1. Target species

Cattle (newborn calves).

3.2. Indications for use for each target species

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.

3.3. 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.

3.4. Special warnings

None.

3.5. Special precautions for use

Special precautions for safe use in the target species:

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 veterinary medicinal 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 halofuginone or any of the excipients should administer the veterinary medicinal product with caution.

Repetitive contact with the veterinary medicinal product may lead to skin allergies.

Avoid skin, eye or mucosal contact with the veterinary medicinal product.

Wear protective gloves while handling the veterinary medicinal product.

In case of skin and eye contact wash the exposed area thoroughly with clean water. If eye irritation persists, seek medical advice immediately and show the package leaflet or the label to the physician.

Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6. Adverse events

Cattle (newborn calves):

Rare (1 to 10 animals / 10 000 animals treated):	Diarrhoea ¹
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¹ an increase in the level of diarrhoea has been observed

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7. Use during pregnancy, lactation or lay

Not applicable.

3.8. Interaction with other medicinal products and other forms of interaction

None known.

3.9. Administration routes and dosage

For oral use in calves after feeding.

The dosage is: 100 µg of halofuginone / kg body weight (bw), once a day for 7 consecutive days; i.e. 2 ml of veterinary medicinal product / 10 kg bw, once a day for 7 consecutive days.

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

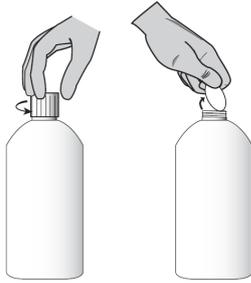
Once the first calf has been treated, all the forthcoming new-born calves must be systematically treated as long as the risk for diarrhoea due to *C. parvum* persists.

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

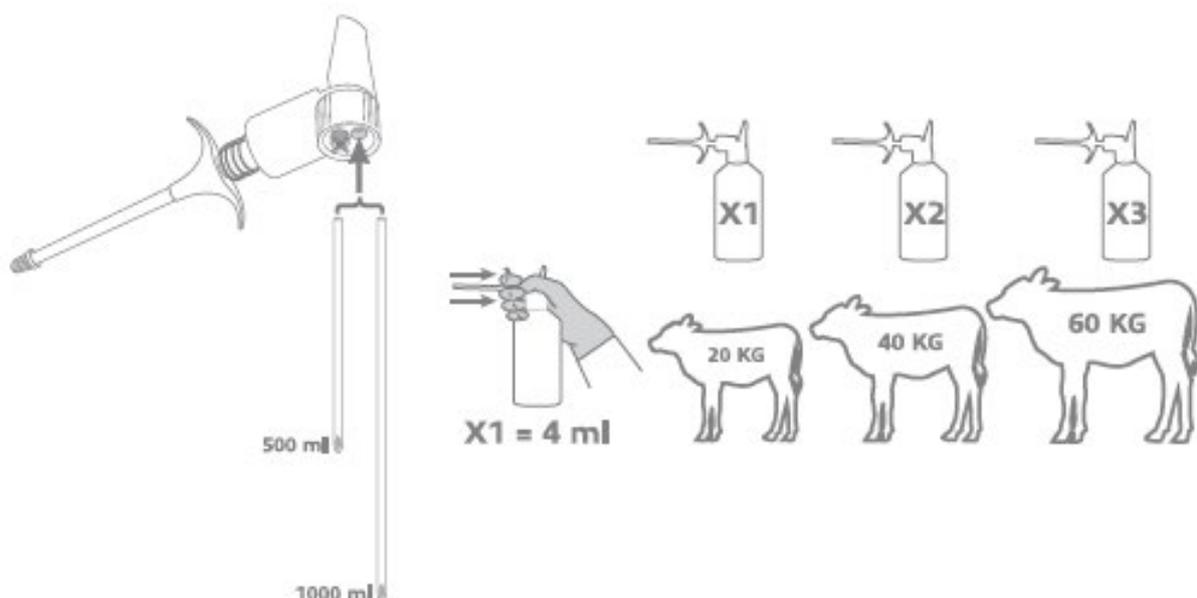
Bottle with a pump: To ensure a correct dosage, the most appropriate metering pump should be selected, depending on the weight of the animals to be treated. In cases where the dosing pump is unsuitable for the weight of animals to be treated, either a syringe or any other appropriate device can be used.

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 bottle) 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.



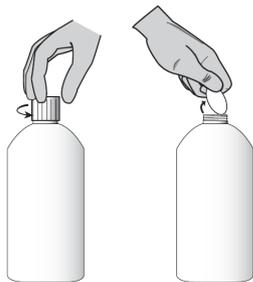
- 3) Remove the protector cap from the tip of the nozzle of the pump.
- 4) Prime the pump by pressing the trigger gently, until a drop appears at the tip of the nozzle.
- 5) Restrain the calf and insert the nozzle of the metering pump into its mouth.
- 6) Pull the trigger of the metering pump completely 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).
For lighter or heavier animals, a precise calculation should be performed (2 ml/10 kg bw).
- 7) Continue using until the bottle is empty. If veterinary medicinal 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.



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 bottle) 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.

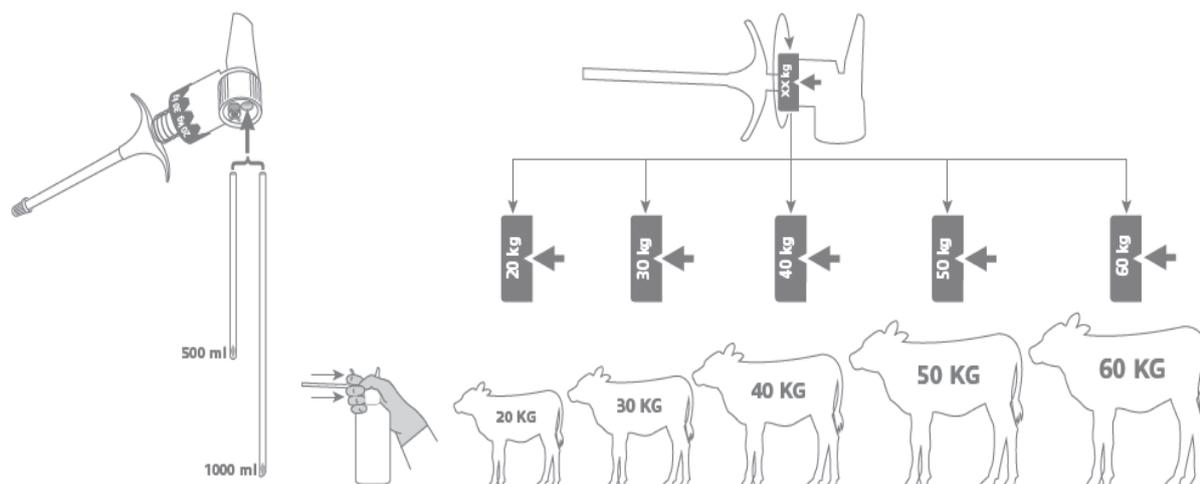
7) Restrain the calf and insert the nozzle of the metering pump into its mouth.

8) Pull the trigger of the metering pump completely for release of the adequate dose.

9) Continue using until the bottle is empty. If veterinary medicinal 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.



3.10. Symptoms of overdose (and where applicable, emergency procedures and 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.

3.11. Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12. Withdrawal periods

Meat and offal: 13 days.

4. PHARMACOLOGICAL INFORMATION

4.1. ATCvet code: QP51AX

4.2. Pharmacodynamics

The active substance, halofuginone, is an antiprotozoal agent of the quinazolinone derivatives group (nitrogenous polyheterocycles). Halofuginone lactate is a salt whose antiprotozoal properties and efficacy against *Cryptosporidium parvum* have been demonstrated both in *in vitro* conditions and in artificial and natural infections. The compound has a cryptosporidiostatic effect on *Cryptosporidium parvum*. It is mainly active on the free stages of the parasite (sporozoite, merozoite). The concentrations to inhibit 50 % and 90 % of the parasites, in an *in vitro* test system, are $IC_{50} < 0.1 \mu\text{g/ml}$ and IC_{90} of $4.5 \mu\text{g/ml}$, respectively.

4.3. Pharmacokinetics

The bioavailability of the drug in the calf following single oral administration is about 80 %. The time necessary to obtain the maximum concentration T_{max} is 11 hours. The maximum concentration in plasma C_{max} is 4 ng/ml. The apparent volume of distribution is 10 l/kg. The plasmatic concentrations of halofuginone after repeated oral administrations are comparable to the pharmacokinetic pattern after single oral treatment. Unchanged halofuginone is the major component in the tissues. Highest values have been found in the liver and the kidney. The product is mainly excreted in the urine. The terminal elimination half-life is 11.7 hours after intravenous administration and 30.84 hours after single oral administration.

5. PHARMACEUTICAL PARTICULARS

5.1. Major incompatibilities

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

5.2. Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 6 months.

5.3. Special precautions for storage

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

5.4. Nature and composition of immediate packaging

Cardboard box containing one 500 ml bottle (high-density polyethylene) containing 490 ml of solution or one 1 000 ml bottle containing 980 ml of solution, sealed with a high density polyethylene cap, with or without a metering pump, with two different lengths dip tubes (22 and 24 cm) made of ethylene-vinyl acetate.

Boxes with a metering pump:

4 ml pump

Each package also contains a plastic metering pump delivering 4 ml volumes and two dip tubes (one to fit a 500 ml bottle and one to fit a 1 000 ml bottle).

4 to 12 ml pump

Each package also contains a plastic metering pump delivering 4 to 12 ml and two dip tubes (one to fit a 500 ml bottle and one to fit a 1 000 ml bottle).

Not all pack sizes may be marketed.

5.5. Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as halofuginone may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/18/234/001-006

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 08/02/2019

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None.

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

2. STATEMENT OF ACTIVE SUBSTANCES

Halofuginone (as lactate salt) 0.50 mg/ml

3. PACKAGE SIZE

490 ml

980 ml

Carton with bottle only

Refill



Carton with bottle and dosing device



4. TARGET SPECIES

Cattle (newborn calves).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Withdrawal periods: Meat and offal: 13 days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 6 months.

9. SPECIAL STORAGE PRECAUTIONS

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



10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

14. MARKETING AUTHORISATION NUMBERS

EU/2/18/234/001 (490 ml bottle)
EU/2/18/234/002 (980 ml bottle)
EU/2/18/234/003 (490 ml bottle + 4 ml dosing pump)
EU/2/18/234/004 (980 ml bottle + 4 ml dosing pump)
EU/2/18/234/005 (490 ml bottle + 4-12 ml dosing pump)
EU/2/18/234/006 (980 ml bottle + 4-12 ml dosing pump)

15. 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

2. STATEMENT OF ACTIVE SUBSTANCES

Halofuginone (as lactate salt) 0.5 mg/ml

3. TARGET SPECIES

Cattle (newborn calves).

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

Oral use.

5. WITHDRAWAL PERIODS

Withdrawal periods: Meat and offal: 13 days.

6. EXPIRY DATE

Exp. {mm/yyyy}

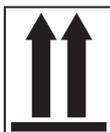
Once opened use within 6 months.

Once broached, use by ...

7. SPECIAL STORAGE PRECAUTIONS

Keep the bottle in the outer carton in order to protect from light.

Store upright in the original packaging.



8. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Kriptazen 0.5 mg/ml oral solution for calves

2. Composition

Each ml contains:

Active substances:

Halofuginone (as lactate salt)	0.50 mg
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Excipients:

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

Clear yellow solution.

3. Target species

Cattle (newborn calves).

4. Indications for use

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. Special warnings

Special warnings:

None.

Special precautions for safe use in the target species:

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 veterinary medicinal 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 halofuginone or any of the excipients should administer the veterinary medicinal product with caution.

Repetitive contact with the veterinary medicinal product may lead to skin allergies.

Avoid skin, eye or mucosal contact with the veterinary medicinal product.

Wear protective gloves while handling the veterinary medicinal product.

In case of skin and eye contact wash the exposed area thoroughly with clean water. If eye irritation persists, seek medical advice immediately and show the package leaflet or the label to the physician.

Wash hands after use.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose:

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.

Major incompatibilities:

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

7. Adverse events

Cattle (newborn calves):

Rare (1 to 10 animals / 10 000 animals treated):
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Diarrhoea ¹

¹ an increase in the level of diarrhoea has been observed

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

For oral use in calves after feeding.

The dosage is: 100 µg of halofuginone / kg body weight (bw), once a day for 7 consecutive days; i.e. 2 ml of veterinary medicinal product / 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

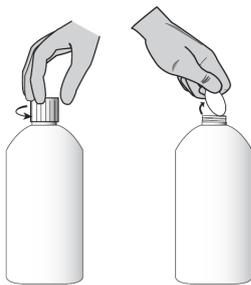
[NOTE: The package leaflet on the market shall mention either the 4 ml pump or the 4 to 12 ml pump or the refill bottle without a pump as appropriate.]

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

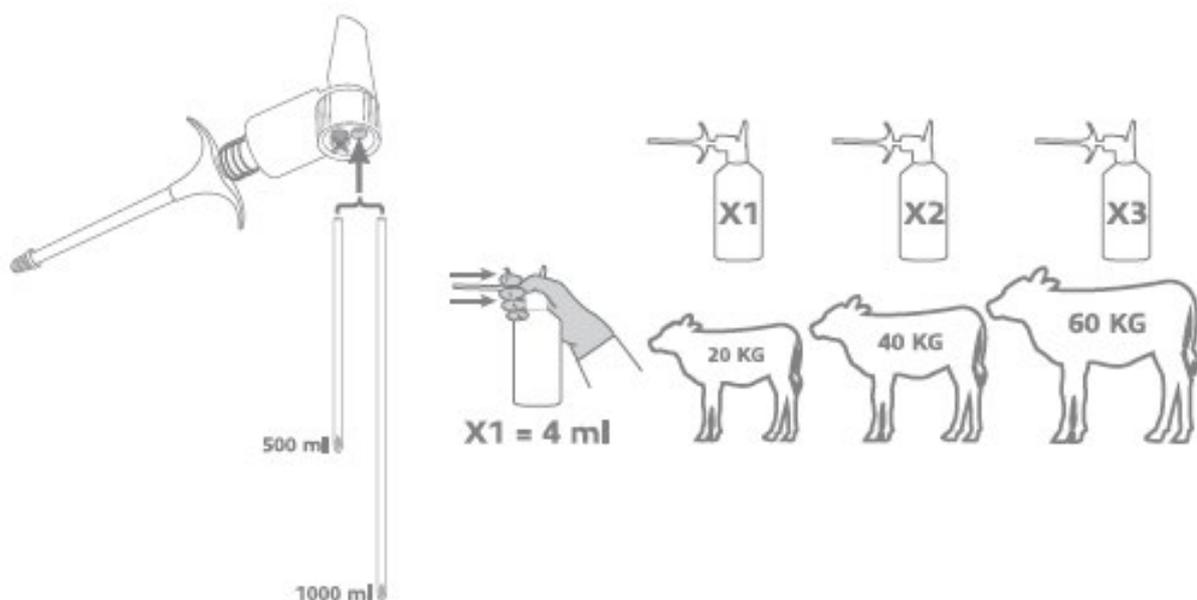
[Bottle with a 4 ml pump:] To ensure a correct dosage, the most appropriate metering pump should be selected, depending on the weight of the animals to be treated. In cases where the dosing pump is unsuitable for the weight of animals to be treated, either a syringe or any other appropriate device can 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.



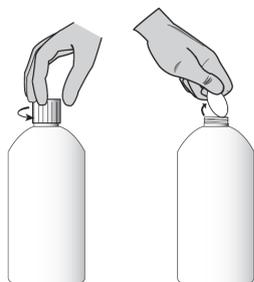
- 3) Remove the protector cap from the tip of the nozzle of the pump.
- 4) Prime the pump by pressing the trigger gently, until a drop appears at the tip of the nozzle.
- 5) Restrain the calf and insert the nozzle of the metering pump into its mouth.
- 6) Pull the trigger of the metering pump completely 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 veterinary medicinal 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.



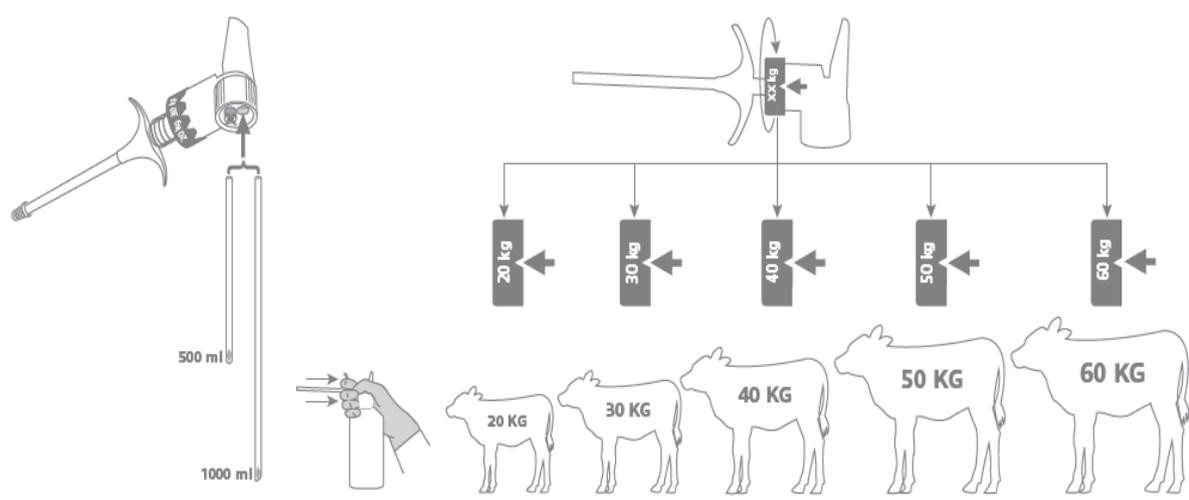
[Bottle with a 4 to 12 ml pump:] To ensure a correct dosage, the most appropriate metering pump should be selected, depending on the weight of the animals to be treated. In cases where the dosing pump is unsuitable for the weight of animals to be treated, either a syringe or any other appropriate device 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 veterinary medicinal 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.



10. Withdrawal periods

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. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 6 months.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as halofuginone may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/18/234/001-006

Pack sizes:

Cardboard box with a 500 ml bottle containing 490 ml of solution or a 1 000 ml bottle containing 980 ml of solution, with or without a dosing pump.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

VIRBAC
1^{ère} avenue 2065 m LID
06516 Carros
France

Local representatives and contact details to report suspected adverse events:

België/Belgique/Belgien

VIRBAC BELGIUM NV
Esperantolaan 4
BE-3001 Leuven
Tel nr +32-(0)16 387 260
phv@virbac.be

Република България

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