# 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 substance:**

| | |
|---|---|
| Halofuginone<br>(as lactate salt) | 0.50 mg |

**Excipients:**

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

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Oral solution.
Clear yellow solution.

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Cattle (newborn calves).

### 4.2 Indications for use, specifying the target species

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 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.

### 4.3 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.

## 4.4 Special warnings

None.

## 4.5 Special precautions for use

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.

## 4.6 Adverse reactions (frequency and seriousness)

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).

## 4.7 Use during pregnancy, lactation or lay

Not applicable.

## 4.8 Interaction with other medicinal products and other forms of interaction

None known.

## 4.9 Amounts to be administered and administration route

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.

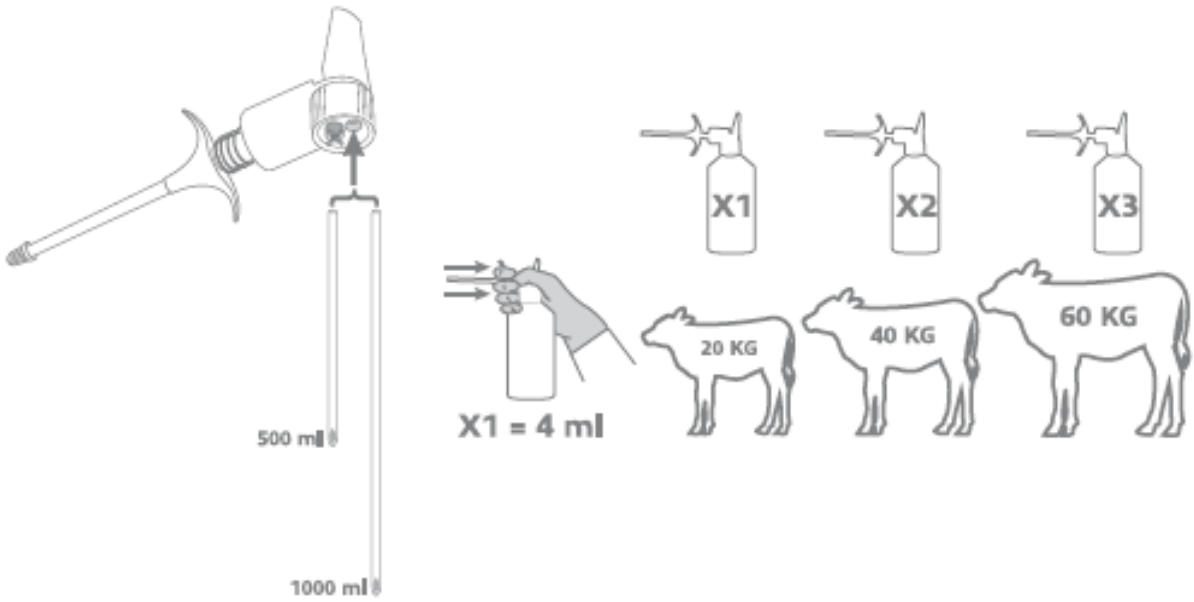
Bottle without a pump: To ensure a correct dosage, the use of either a syringe or any appropriate device for oral administration is necessary.

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 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.

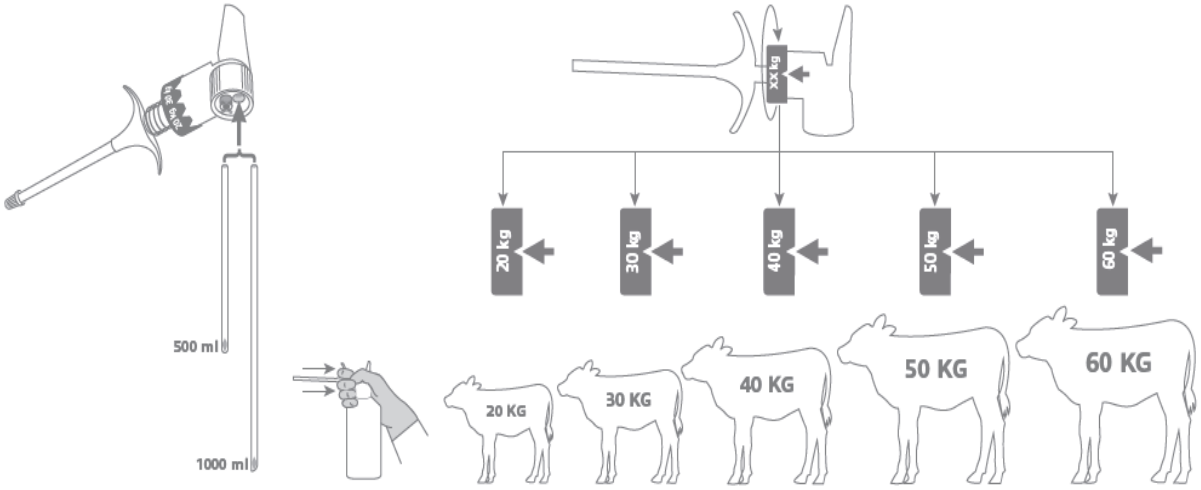



**4 to 12 ml pump**

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 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.




## 4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

## 4.11 Withdrawal period(s)

Meat and offal: 13 days.

# 5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Other antiprotozoal agents, halofuginone.
ATCvet code: QP51AX08.

## 5.1 Pharmacodynamic properties

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 (sporozoïte, merozoïte). The concentrations to inhibit 50% and 90% of the parasites, in an *in vitro* test system, are $IC_{50}$ < 0.1 µg/ml and $IC_{90}$ of 4.5 µg/ml, respectively.

## 5.2 Pharmacokinetic particulars

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 IV administration and 30.84 hours after single oral administration.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Benzoic acid (E 210)
Lactic acid (E 270)
Tartrazine (E 102)
Water, Purified

### 6.2 Major Incompatibilities

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

### 6.3 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.

### 6.4 Special precautions for storage

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

### 6.5 Nature and composition of immediate packaging

Cardboard box containing one 500 ml bottle (high-density polyethylene) containing 490 ml of solution or one 1000 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 1000 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 1000 ml bottle).

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
The product should not enter watercourses as this may be dangerous for fish and other aquatic organisms.

## 7. MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

## 8. MARKETING AUTHORISATION NUMBER

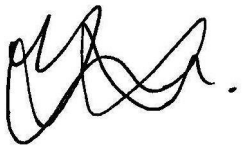
05653/5012

## 9. DATE OF FIRST AUTHORISATION

08 February 2019

## 10. DATE OF REVISION OF THE TEXT

August 2023



Approved: 18 August 2023