SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HALAGON 0.5 mg/ml oral solution for calves

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Halofuginone (as lactate salt)	0.50 mg
Equivalent to 0.6086 mg of halofuginone lactate	

Excipients:

Benzoic acid (E210)	1 mg
Tartrazine (E102)	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 newborn calves:

- Prevention of diarrhoea due to diagnosed *Cryptosporidium parvum* infection, 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* infection.
  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 case 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. An appropriate device for oral administration is included. For treatment of anorexic calves, the product should be administered in half a liter 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 very 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 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).

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 body weight (bw) / once a day for 7 consecutive days, i.e. 4 ml of HALAGON / 20 kg bw / once a day for 7 consecutive days.

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

- 35 kg < calves ≤ 45 kg: 8 ml of HALAGON once a day during 7 consecutive days
- 45 kg < calves < 60 kg: 12 ml of HALAGON 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, an appropriate metering pump for administration of 'HALAGON' is included.

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) Put the protector cap back on the nozzle.

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.

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 (E210)
Lactic acid (E270)
Tartrazine (E102)
Water, purified

6.2. Major incompatibilities

Not applicable.

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.

6.5. Nature and composition of immediate packaging

- Cardboard box containing one bottle (high-density polyethylene) of 290 ml oral solution.
- Cardboard box containing one bottle (high-density polyethylene) of 490 ml oral solution.
- Cardboard box containing one bottle (high-density polyethylene) of 980 ml oral solution.

Each bottle is sealed with a polypropylene cap.
Each package also contains a 4 ml metering pump that consists of several components made out of high, low and linear low-density polyethylene, polypropylene, stainless steel and silicone.

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

Emdoka bvba
J. Lijsenstraat 16
B-2321 Hoogstraten
Belgium

8. MARKETING AUTHORISATION NUMBER

Vm 34534/5001

9. DATE OF FIRST AUTHORISATION

13 December 2016

10. DATE OF REVISION OF THE TEXT

October 2021

Approved: 14 October 2021