

CRYPTISEL 0.5 mg/ml

Halofuginone oral solution for calves

DESTROY THE INVADER

PREVENTION AND TREATMENT OF CRYPTOSPORIDIOSIS IN CALVES



Qualitative and quantitative composition

Each ml contains: Halofuginone 0.50 mg (equivalent to 0.6086 mg of Halofuginone lactate).

Pharmaceutical Form

Oral solution. Clear yellow solution.

Target species

Cattle (newborn calves).

Indications for use, specifying the 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.

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.

Special warnings for each target species None.

Special precautions for use

LIVISTO Int'l

(Barcelona) Spain.

Av. Universitat Autònoma, 29

08290 Cerdanyola del Vallès

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.
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 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, eye and mucosa contact wash the exposed area thoroughly with clean water. If eye irritation persists, seek medical advice. Wash hands after use.

Adverse reactions (frequency and seriousness)
In very rare cases, an increase in the level of
diarrhoea has been observed in treated animals.

Use during pregnancy, lactation or lay Not applicable.

Interaction with other medicinal products and other forms of interaction

None known.

Amounts to be administered and administration route

For oral use in calves after feeding. The dosage is: $100~\mu g$ /kg b.w. / once a day for 7 consecutive days (2 ml/10 kg b.w. / once a day for 7 consecutive days). 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.

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

As clinical signs of toxicity may occur at twice the therapeutic dose, it is necessary to apply the recommended dosage strictly. Clinical signs 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.

Withdrawal periods

Meat and offal: 13 days.

Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 30 months.

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



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

Nature and composition of immediate packaging

PET bottles of 300 ml (containing 290 ml of solution), 500 ml (containing 490 ml of solution) and 1000 ml (containing 980 ml of solution) with a 4 ml metering pump.

Marketing Authorisation Holder

LIVISTO Int'I, S.L. Av. Universitat Autònoma, 29, 08290 Cerdanyola del Vallès (Barcelona), Spain

Reference

- 1. EMA. CRYPTISEL. Summary of product characteristics. 1–6 (2019).
- 2. De Waele, V., Speybroeck, N., Berkvens, D., Mulcahy, G. & Murphy, T. M. Control of cryptosporidiosis in neonatal calves: Use of halofuginone lactate in two different calf rearing systems. *Prev. Vet. Med.* 96, 143–151 (2010).
- 3. Jarvie, B. D. et al. Effect of halofuginone lactate on the occurrence of Cryptosporidium parvum and growth of neonatal dairy calves. *J. Dairy Sci.* 88, 1801–1806 (2005).
- 4. Lefay, D., Naciri, M., Poirier, P. & Chermette, R. Efficacy of halofuginone lactate in the prevention of cryptosporidiosis in suckling calves. *Vet. Rec.* 148, 108–112 (2001).
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- 6. A.C, C., Sanchez-Acedo, C., Quilez, J., Del Cacho, E. & Viu, M. Efficacy of Halofuginone Lactate Against natural Cryptosporidium parvum infections in lambs. Res. Rev. Parasitol. 59, 41–46 (1999).
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- 9. Trotz-Williams, L. A., Jarvie, B. D., Peregrine, A. S., Duffield, T. F. & Leslie, K. E. Efficacy of halofuginone lactate in the prevention of cryptosporidiosis in dairy calves. Vet. Rec. 168, 509 (2011).

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FORTE Healthcare Ltd. Block 3, Un it 9 CityNorth Business Campus, Stamullen, Co. Meath, Ireland Tel: +353 1 841 7666 Fax: +353 1 841 6353 enquiries@fortehealthcare.com www.fortehealthcare.com Technical enquiries: vets@fortehealthcare.com



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CRYPTISEL 0.5 mg/ml

Halofuginone oral solution for calves

Halofuginone is a potent anticoccidial that belongs to the chemical group of Quinazolinones and it has an anti-protozoal activity by affecting the early free-living stages of the parasite (merozoites and sporozoites).1

The anti-protozoal activity of halofuginone allows a cryptosporidiostatic action, with the following effects:



Reduction of oocyst shedding



Delay in the onset of the infection



Reduction of clinical symptoms

onset of clinical signs.



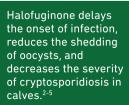
THE EFFICACY OF HALOFUGINONE

prophylactic use. Its action in delaying the onset of infection

ensures the calves are more immunologically competent at the

Reduction of the severity of the disease

Good colostrum management and meticulous hygiene in calf accommodation will play a key role in the success of the treatment.



Halofuginone reduces C. parvum multiplication by more than 90%.6

Calves with Cryptosporidiumassociated diarrhoea show an immediate improvement in clinical signs after treatment with halofuginone.3,7

Treatment with halofuginone reduces calf mortality associated with C. parvum and helps maintain normal weight gain.5,8,9

A combination of halofuginone treatment alongside good hygiene and colostrum management is the most effective method to reduce the risk of cryptosporidiosis.2

DESTROY THE INVADER

With CRYPTISEL you can "destroy the invader" by greatly reducing the oocyst shedding of Cryptosporidium parvum thus achieving a better control of neonatal diarrhoea in calves.



INDICATIONS

• 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.

Halofuginone lactate is recommended for both therapeutic and WITHDRAWAL TIME

Meat and offal 13 days.



DOSAGE

For oral use in calves after feeding.

100 µg of halofuginone / kg b.w. / once a day for 7 consecutive days

2 ml of CRYPTISEL / 10 kg b.w. / once a day for 7 consecutive days. The consecutive treatments should be done at the same time each day.

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











