HALOFUSOL

0.5 MG/ML ORAL SOLUTION FOR CALVES

0.50 mg/ml Halofuginone (equivalent to 0.6086 mg of halofuginone lactate)

DATA SHEET

INDICATIONS

In new born calves:

• Prevention of diarrhoea due to diagnosed *Cryptosporidium parvum* in farms with history of cryptosporidiosis.
• Reduction of diarrhoea due to diagnosed *Cryptosporidium parvum.*

BENEFITS

- Reduction of oocysts excretion has been demonstrated
- Simple oral dosing for new born calves after feeding colostrum, milk or milk replacer
- Administer directly or mixed in with electrolyte solution for anorexic calves
- Short meat withdrawal period of 13 days

LIST No	UNIT PACKAGE
1HAL001	250ml & Pump
1HAL002	500ml & Pump
1HAL003	1L & Pump
1HAL007	1L Refill
8APL035	Halofusol Pump Kit

See reverse for Administration & Dosage

HALOFUSOL

0.5 mg/ml oral solution for calves

COMPOSITION
A clear yellow oral solution containing 0.50 mg/ml Halofuginone (equivalent to 0.6086 mg of halofuginone lactate).

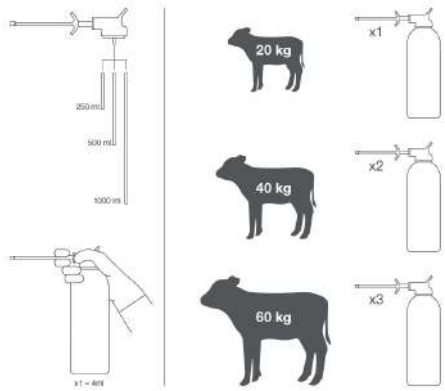
TARGET SPECIES
Cattle (newborn calves).

INDICATIONS FOR USE
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 life.
- 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.

AMOUNTS TO BE ADMINISTERED AND ADMINISTRATION ROUTE
For oral use in calves after feeding.
The dosage is: 100 µg of halofuginone base / kg bw / once a day for 7 consecutive days, i.e. 4 ml of the product / 20 kg bw / once a day for 7 consecutive days.
However, in order to make the product treatment easier, a simplified dosage scheme is proposed:
- 35 kg < calves ≤ 45 kg: 8 ml of the product once a day during 7 consecutive days
- 45 kg < calves < 60 kg: 12 ml of the product 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, the use of either the metering pump included or any appropriate device for oral administration is necessary.
In case of using the metering pump included, it should not be used upside down, and has to be proceed as follows:



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 calf's 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. Unscrew the metering pump on the bottle.
7. Close the bottle with the screw cap.
8. Pull twice or three times in order to empty the remained product in the metering pump.
9. 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.

WITHDRAWAL PERIOD
Meat and offal: 13 days

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 case of hypersensitivity to the active substance or to any of the excipients.

SPECIAL WARNINGS
None.

SPECIAL PRECAUTIONS FOR USE IN ANIMALS
Administer after colostrum feeding, or after milk or milk replacer feeding only, using either the metering pump included or any 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
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 and eye contact with the product. In case of skin and eye contact wash the exposed area thoroughly with clean water. If an eye irritation persists, seek medical advice. Wear protective gloves while handling the product. Wash hands after use.

ADVERSE REACTIONS
In very rare cases (less than 1 animal in 10,000 animals treated, including isolated reports), an increase in the level of diarrhoea has been observed in treated animals.

INTERACTION WITH OTHER MEDICINAL PRODUCTS
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.

PHARMACODYNAMIC PROPERTIES
Pharmacotherapeutic group: Other antiprotozoal agents, halofuginone.
The active substance, Halofuginone, is an antiprotozoal agent of the quinazolinone derivatives group (nitrogenous polyheterocycles). Halofuginone lactate (RU 38788) is a salt whose antiprotozoal properties and activity 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.

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.

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

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

SPECIAL PRECAUTIONS FOR STORAGE
This veterinary medicinal product does not require any special storage conditions.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCTS
The product should not enter water courses as this may be dangerous for fish and other aquatic organisms. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

LEGAL CATEGORY
POM

MARKETING AUTHORISATION HOLDER
Laboratorios Karizoo S.A.
Pol. Ind. La Borda
Mas Pujades, 11-12
08140 Caldes de Montbui
Barcelona
Spain

MARKETING AUTHORISATION NUMBER
VPA10786/007/001

DISTRIBUTED IN IRELAND BY
Bimeda Animal Health Limited
2, 3 & 4 Airton Close,
Airton Road,
Tallaght,
Dublin 24.
Ireland Tel: +353 (0) 1 466 7900

Use Medicines Responsibly

A full product SPC is available on request from Bimeda or alternatively can be found on the HPRA website.

TAKE TIME OBSERVE LABEL DIRECTIONS

www.bimeda.ie

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