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 neonatal calves:

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

BENEFITS

- Reduction of oocyst excretion has been demonstrated
- Simplified oral dosing treatment regime
- Administer directly or mixed in with electrolyte solution

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

PRESENTATION
A clear, yellow solution containing 0.5mg/ml of halofuginone (equivalent to 0.6086 mg/ml of halofuginone lactate).

TARGET SPECIES
Cattle (newborn calves).

INDICATIONS FOR USE
In new born calves:
Prevention of diarrhoea due to diagnosed *Cryptosporidium parvum* on 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 of the onset of diarrhoea.
In both cases, the reduction of oocyst excretion has been demonstrated.

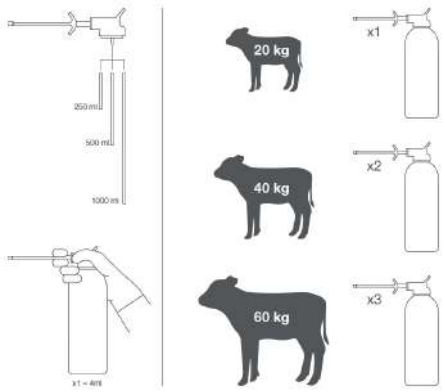
CONTRAINDICATIONS
Do not use on an empty stomach.
Do not use in cases of diarrhoea established for more than 24 hours and in weak animals.
Do not use in known cases of hypersensitivity to the active substance or to any of the excipients.

SPECIAL PRECAUTIONS FOR USE IN ANIMALS
Administer after colostrum, milk or milk replacer feeding only, using either the metering pump included or an appropriate device for oral administration. Do not administer 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 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.

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 - 44 kg calves : 8 ml of the product once a day for 7 consecutive days
45 - 60 kg calves : 12 ml of the product once a day for 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 an appropriate device for oral administration is necessary. If using the metering pump included, it should not be used upside down, and proceed as follows:

1) Screw the metering pump onto 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 at the tip 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 to release a dose equal to 4 ml of solution. Pull twice or three times, respectively, for administration of the desired volume (8 ml for calves of 35 – 44 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 two 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.

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 recumbency. Should clinical signs of overdose occur the treatment must be stopped immediately and the animal fed unmedicated milk or milk replacer. Rehydration may be necessary.

WITHDRAWAL PERIOD(S)
Meat and offal: 13 days

PHARMACODYNAMIC PROPERTIES
The active substance, halofuginone, is an antiprotozoal agent of the quinazolinone derivative group (nitrogenous polyheterocycles). Halofuginone lactate 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 *C. parvum*. It is mainly active on the free stages of the parasite (sporozoïte, merozoïte).

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 plasma 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 30.84 hours after single oral administration.

EXCIPIENTS
Benzoic acid (E 210), Tartrazine (E 102), Lactic Acid (E 270), Purified water.

INCOMPATIBILITIES AND INTERACTIONS
In the absence of compatibility studies, this product must not be mixed with other veterinary medicinal products. No known interaction with other medicinal products and other forms of interaction.

SHELF LIFE
Shelf life of the product as packaged for sale: 30 months.
Shelf life after first opening the immediate packaging: 6 months.

STORAGE
Does not require any special storage conditions.

DISPOSAL
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-V

MARKETING AUTHORISATION NUMBER
Vm 31223/4009

MARKETED IN THE UK BY
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TAKE TIME OBSERVE LABEL DIRECTIONS

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