

Consumer leaflet for a Veterinary Product

This medicine is marketed according to a veterinarian's prescription only.
For animal use only

1. Name of the veterinary medicine, form and strength

Halofusol 0.5 mg/ml Veterinary,
Oral Solution

2. Active ingredient

Halofuginone (as lactate) 0.50 mg/ml

Inactive ingredients:

Benzoic acid (E210) 1.00 mg/ml

Tartrazine (E 102) 0.03 mg/ml

A full list of excipients is detailed in section 13 – “Additional information”.

3. What is the medicine intended for

In new born calves:

- Prevention of diarrhea due to diagnosed *Cryptosporidium parvum*, in farms with history of cryptosporidiosis infection. Administration should start in the first 24 to 48 hours of age.
- For reduction of diarrhea due to diagnosed *Cryptosporidium parvum*. Administration should start within 24 hours after the onset of diarrhea.

In both cases, the reduction of oocysts excretion has been demonstrated.

Therapeutic group: Antiprotozoal agent, Quinazolinone derivate.

4. Contra-indications

Do not administer on an empty stomach.

Do not administer in case where diarrhea persists for more than 24 hours and in weak calves.

Do not administer to cows producing milk for human consumption.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

5. Side effects

Cattle (newborn calf):

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Diarrhoea ¹
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¹an increase in the level of diarrhoea has been observed.

Side effects can be reported to the Ministry of Health by clicking on the link "Adverse Drug Reactions Report" that appears on the home page of the Ministry of Health web site (www.health.gov.il), which leads to an online form for reporting side effects. Alternatively you can use the following link: <https://sideeffects.health.gov.il/>

6. Target animals: New born calves.

7. Dosage and administration

For oral use after calves' feeding.

The dosage is 100 mcg of Halofuginone / kg body weight / once a day for 7 consecutive days, that is, 2 ml of Halofusol 0.5 mg/ml veterinary for every 10 kg body weight, once a day for 7 consecutive days.

However, in order to make administration simpler, the dosage may be administered according to the following scheme:

For calves with a body weight of 35 kg to 45 kg inclusive, administer 8 ml of Halofusol 0.5 mg/ml once a day for 7 consecutive days. For calves with a body weight of 45 kg to 60 kg, administer 12 ml of

Halofusol 0.5 mg/ml once a day for 7 consecutive days.

For calves with a smaller or larger body weight than above, calculate the dosage precisely (according to 2 ml/10 kg body weight).

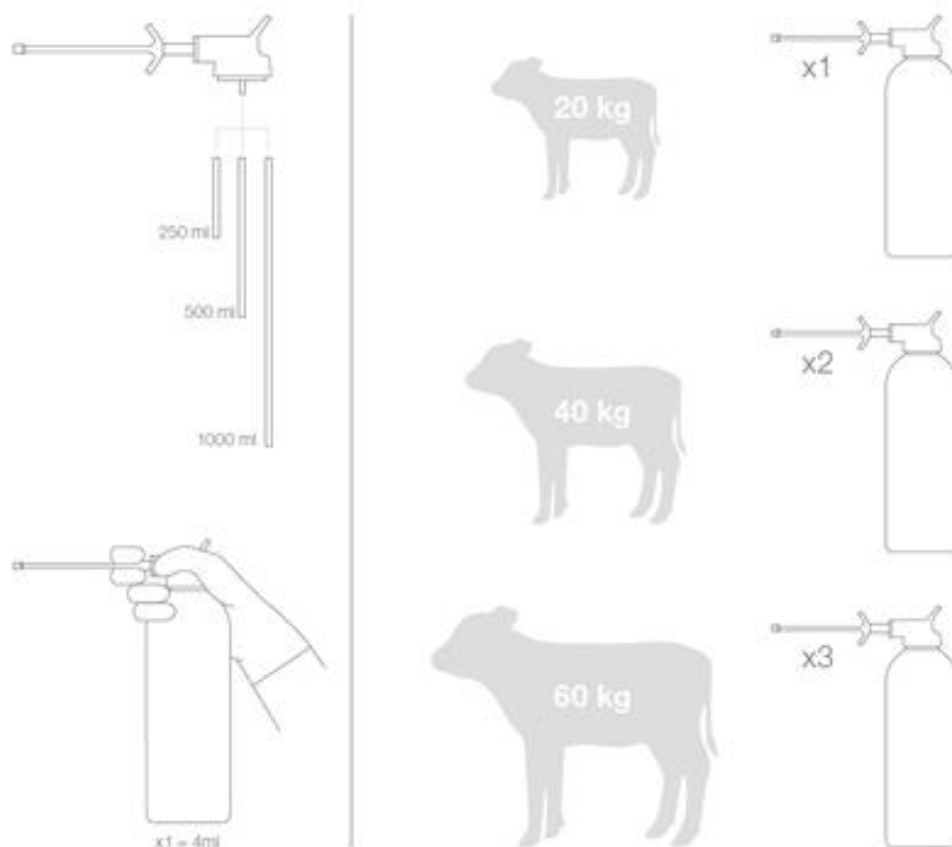
8. How to use the product

Underdosing could result in ineffective use and may promote resistance development.

To ensure a correct dosage, body weight should be determined as accurately as possible. The use of either the metering pump included or a suitably calibrated measuring equipment is recommended. The medicine should be administered at the same time each day during the treatment period. Once the first calf has been treated, all the forthcoming new born calves must be treated as long as the risk of diarrhea due to *Cryptosporidium parvum* persists.

If using the metering pump included, it should not be used upside down and must be used 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 has not been used for a few days), carefully pump until 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 to release a 4-ml dose of solution. Pull two or three times, respectively, to administer 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 from the bottle.
- 7) Close the bottle with the screw cap.
- 8) Pull two or three times in order to empty the remaining veterinary medicinal product from the metering pump.
- 9) Put the protector cap back on the nozzle.



9. Withdrawal period: For meat slaughter: 13 days.

10. Warnings

Special warnings regarding the use of medicine during treatment in target animal

Unnecessary use of antiparasitics or use deviating from the instructions given in the leaflet may increase the resistance and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or risk of infection based on its epidemiological features, for each herd.

Special warnings regarding the safety of use of medicine in animals

Administer the medicine after colostrum feeding, milk or milk replacer feeding only, using either the metering pump included or a syringe or any 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 liter of an electrolyte solution. The calves should receive enough colostrum according to good breeding practice.

Special warnings regarding the safety of the person handling the product

Repetitive contact with the product may lead to skin allergies.

Avoid skin, eye and mucosal contact with the veterinary medicinal product.

People with known hypersensitivity to halofuginone should administer the veterinary medicinal product with caution.

Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product.

In case of accidental skin or eye contact wash the exposed area thoroughly with clean water.

If eye irritation persists, seek medicinal advice and show the package leaflet or the label to the physician.

Wash hands after use.

Pregnancy and lactation in treated animal: Not applicable.

Interactions with other medicines and other types of interactions: 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.

Major incompatibility: None known

11. Storage instructions

- Avoid poisoning! This medicine, and any other medicine, must be kept in a closed place outside the reach of children and/or infants to prevent accidental poisoning.
- Do not use the medicine after its expiration date (exp. date) as it appears on the package. The expiration date refers to the last day of the stated month.
- Storage conditions: Store below 25°C. Store in the outer carton package to protect from light.
- Shelf life after first package opening- 6 months.

12. Instructions for disposing of the product / remaining product at the end of its use

Medicines should not be disposed of via wastewater or household waste.

This veterinary medicinal product should not enter water courses as halofuginone may be dangerous for fish and other aquatic organisms.

Any unused veterinary product or waste materials derived from using veterinary product should be disposed of as toxic waste, do not throw to sewer.

Ask your veterinarian or pharmacist how to dispose of medicines no longer required.

13. Additional information

- In addition to the active substance, the medicine also contains: Purified water, S-Lactic Acid (E270), Benzoic Acid (E210), Tartrazine (E102)
- What does the medicine look like– clear yellow solution.
- Package: HDPE bottle containing 250, 500 or 1000 ml oral solution, in external carton package with 4 ml metering pump. Not all package sizes may be marketed.

Registration holder: VETMARKET LTD., 23 HACHORESH WAY, INDUSTRIAL PARK MODI'IN REGION

Manufacturer: LABORATORIOS KARIZOO S.A., BARCELONA, SPAIN.

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Registration number of this medicine in the Ministry of Health State Medicine Registry: 178-67-36858-99