CONSUMER PACKAGE INSERT FOR VETERINARY MEDICINAL PRODUCT

The medicine is dispensed with a veterinarian's prescription only
For animal use only

1. **NAME OF THE VETERINARY MEDICINAL PRODUCT, ITS FORM AND STRENGHT:**
   Halocur Veterinary
   Oral Solution

2. **ACTIVE INGREDIENT:**
   Halofuginone base (as lactate) 0.50 mg/ml

   Inactive substances
   Benzoic acid 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 MEDICINAL PRODUCT 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. **CONTRAINDICATIONS:**
   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]

[1] an increase in the level of diarrhoea has been observed.

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting Side Effects due to Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

https://sideeffects.health.gov.il

6. TARGET SPECIES:

New born calves.

7. METHOD OF ADMINISTRATION AND DOSAGE:

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 Halocur 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 Halocur once a day for 7 consecutive days.
For calves with a body weight of 45 kg to 60 kg, administer 12 ml of Halocur 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 favour resistance development.

To ensure a correct dosage, body weight should be determined as accurately as possible.

The use of 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.

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 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 litre of an electrolyte solution. The claves 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 madicines 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, should be kept in a closed place, out of the reach and sight of children and/or infants in order to protect from poisoning.
- Do not use the medicine after the expiry date (exp. Date) appearing on the package. The expiry date refers to the last day of that month.
- Storage conditions: Store below 25°C.
- After first opening use within 6 months.

12. INSTRUCTIONS REGARDING DISPOSAL OF THE MEDICINAL PRODUCT/REMNANTS OF THE MEDICINAL PRODUCT AFTER 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 veterinary or pharmacist how to dispose of medicines no longer required.

13. ADDITIONAL INFORMATION:

- In addition to the active substance (s), the medicine also contains:
  Lactic Acid, Benzoic Acid, Tartrazine E 102, Water

- What the medicine looks like: Canary yellow homogenous clear solution.

- The package:
  500 ml HDPE bottle containing 490 ml of oral solution.
  1000 ml HDPE bottle of containing 980 ml of oral solution.
  Not all pack sizes may be marketed.

- **Registration holder and address:** Intervet Israel Ltd., Industrial zone Neve Ne'eman, Hod Hasharon 45240.

- **Manufacturer name and address:**
  Intervet Productions SA, Rue de Lyons, 27460 Igoville, France

- Revised on December 2024.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 155-24-34248-00