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 MEDICINAL PRODUCT AND ITS FORM:**
   Halocur Veterinary
   Oral Solution

2. **COMPOSITION:**
   Active substance
   Halofuginone base (as lactate salt) 0.50 mg/ml

   Inactive substances
   Benzoic acid 1.00 mg/ml
   Tartrazine (E 102) 0.03 mg/ml

   The 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: Quinazolinone derivate

4. **CONTRAINDICATIONS:**
   Do not administer on an empty stomach.
   Do not administer in cases where diarrhea persists for more than 24 hours and in weak calves.
   Do not administer to cows producing milk for human consumption.

5. **SIDE EFFECTS:**

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

   If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

   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 in calves after feeding.

The dosage is 100 µg 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 treatment 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:**
To ensure a correct dosage, use a syringe or any appropriate device for oral administration.
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:**
Meat 13 days.

10. **WARNINGS:**
Special warnings
None.

Special warnings relating to use of the medicine in animals
Administer the medicine only after colostrum, milk or milk substitute feeding.
Use only a syringe 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 of a liter of an electrolyte solution. The calves should receive enough colostrum according to good breeding practice.

Special warnings relating to the safety of the person administering the medicinal product
Repetitive contact with the medicine may lead to skin allergies. Avoid eye, skin or mucosal contact. Wear gloves while handling the medicine.
In case of skin and eye contact wash the eye or the exposed skin area thoroughly with clean water. If eye irritation persists, seek medical advice.
Wash hands after using the medicine.

Pregnancy and lactation in treated animal
Not applicable.

Interactions with other medicinal products and other types of interactions
None known.

Overdose
Symptoms of toxicity may occur at twice the recommended dose, therefore it is imperative to administer the recommended dosage accurately. Symptoms of toxicity include diarrhea, blood seen in the feces, decline in milk consumption, dehydration, apathy and prostration.
Should these signs occur, stop giving the medicine immediately and feed the calf with milk or a milk substitute free of medication. Treat dehydration by administration of fluids.

Major incompatibility
None known

11. STORAGE INSTRUCTIONS:

- Avoid poisoning! This medicinal product and any other medicinal products, 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 medicinal product after the expiry date (exp. Date) appearing on the package. The expiry date refers to the last day of that month.
- Storage conditions: Store at a temperature below 25°C.
- Shelf life after first opening: 6 months.

12. INSTRUCTIONS REGARDING DISPOSAL OF THE MEDICINAL PRODUCT/REMNANTS OF THE MEDICINAL PRODUCT AFTER USE:

Prevent the medicine and empty containers reaching water sources and drains, as this may be dangerous for fish and other aquatic organisms.

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

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 2020.

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