PACKAGE LEAFLET:

Cryptisel 0.5 mg/ml oral solution for calves [AT, CY, CZ, DE, EL, ES, HU, IE, IT, LT, LV, NL, PL, PT, RO, SK, UK]
Cryptisel, 0.5 mg/ml oral solution for calves [EE]
Cryptisel vet 0.5 mg/ml oral solution for calves [DK, NO, SE]

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:
Industrial Veterinaria, S.A.
Esmeralda, 19
08950 Esplugues de Llobregat
(Barcelona) Spain

Manufacturer responsible for batch release:
aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell Germany

aniMedica Herstellungs GmbH
Im Südfeld 9
48308 Senden-Bösensell Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cryptisel 0.5 mg/ml oral solution for calves [AT, CY, CZ, DE, EL, ES, HU, IE, IT, LT, LV, NL, PL, PT, RO, SK, UK]
Cryptisel, 0.5 mg/ml oral solution for calves [EE]
Cryptisel vet 0.5 mg/ml oral solution for calves [DK, NO, SE]
Halofuginone

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains:

Active substance:
Halofuginone 0.50 mg
Equivalent to 0.6086 mg of Halofuginone lactate

Excipients:
Benzoic acid (E 210) 1.00 mg
Tartrazine (E 102) 0.03 mg

Clear yellow solution.

4. INDICATION(S)

- 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 age.

- 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.

5. 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 cases of hypersensitivity to the active substance or to any of the excipient(s).

6. ADVERSE REACTIONS

In very rare cases, an increase in the level of diarrhoea has been observed in treated animals.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Cattle (newborn calves).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral use in calves after feeding

The dosage is: 100 µg of halofuginone / kg bw / once a day for 7 consecutive days, i.e. 2 ml of the veterinary medicinal product / 10 kg bw / once a day for 7 consecutive days.

The consecutive treatment should be done at the same time each day.

Once the first calf has been treated, all the forthcoming newborn calves must be systematically treated as long as the risk for diarrhoea due to *C. parvum* persists.

9. ADVICE ON CORRECT ADMINISTRATION

Bottle without a pump: To ensure a correct dosage, the use of an appropriate device for oral administration (e.g. a syringe) is necessary.

Bottle with a pump: To ensure a correct dosage, an appropriate metering pump is included.

1) Insert the suction pipe into the free hole located in the base of the pump cap.
2) Remove the cap of the bottle and screw the pump on.
3) Remove the protector cap from the tip of the nozzle of the pump.
4) 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.
5) Restrain the calf and insert the nozzle of the metering pump into its mouth.
6) Pull the trigger of the metering pump completely for release of a dose that equals 4 ml of solution.
   - For animals weighing from more than 35 kg but less than or equal to 45 kg, pull two times (equivalent to 8 ml)
   - For animals weighing from more than 45 kg but less than or equal to 60 kg, pull three times (equivalent to 12 ml)
7) Unscrew the metering pump on the bottle.
8) Close the bottle with the screw cap.
9) Pull twice or three times in order to empty the remaining product in the metering pump.
10) Put the protector cap back on the nozzle.

The metering pump should not be used upside down.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 13 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Keep the bottle in the outer carton in order to protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening the container: 6 months

12. SPECIAL WARNING(S)

Special precautions for use in animals:
Administer after colostrum feeding, or after milk or milk replacer feeding only, using an appropriate device for oral administration. For treatment of anorexic calves, the veterinary medicinal 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 to animals:
- 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, eye or mucosal contact with the product. Wear protective gloves while handling the product.
- In case of skin, eye and mucosa contact wash the exposed area thoroughly with clean water. If eye irritation persists, seek medical advice.
- Wash hands after use.

Overdose (symptoms, emergency procedures, antidotes):
As clinical signs of toxicity may occur at twice the therapeutic dose, it is necessary to apply the recommended dosage strictly. Clinical signs 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.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.
The product should not enter watercourses as this may be dangerous for fish and other aquatic organisms.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Package sizes:
Cardboard box with 1 bottle of 300 ml (containing 290 ml of solution) with a 4 ml metering pump
Cardboard box with 1 bottle of 300 ml (containing 290 ml of solution)
Cardboard box with 1 bottle of 500 ml (containing 490 ml of solution) with a 4 ml metering pump
Cardboard box with 1 bottle of 500 ml (containing 490 ml of solution)
Cardboard box with 1 bottle of 1000 ml (containing 980 ml of solution) with a 4 ml metering pump
Cardboard box with 1 bottle of 1000 ml (containing 980 ml of solution)

Not all pack sizes may be marketed.