ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

HDPE container (**500 ml and 1000 ml presentations)**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HALOCUR 0.5 mg/ml oral solution for calves

2. STATEMENT OF ACTIVE SUBSTANCE

Halofuginone base (as lactate salt) 0.5 mg/ml

3. PHARMACEUTICAL FORM

Oral solution

4. PACKAGE SIZE

500 ml bottle containing 490 ml of oral solution
1000 ml bottle containing 980 ml of oral solution

5. TARGET SPECIES

New born calves

6. INDICATION(S)

Read package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use in new born calves after feeding.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Meat and offal: 13 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: month/year
Once broached, use within 6 months.

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT ORWASTE MATERIALS, IF ANY

Disposal: read package leaflet*.*

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS ORRESTRICTIONS REGARDING SUPPLY AND USE,

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER(S)

MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
MK7 7AJ

Intervet International B.V.
Wim de Körverstraat 35
NL-5831 AN Boxmeer
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/5037

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> number.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
HALOCUR 0.5 mg/ml oral solution for calves

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

Marketing authorisation holder:
Intervet International B.V.
Wim de Körverstraat 35
NL-5831 AN Boxmeer
The Netherlands

Manufacturer responsible for batch release: Intervet Productions S.A.
Rue de Lyons
27460 Igoville
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

HALOCUR 0.5 mg/ml oral solution for calves

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

The veterinary medicinal product is a canary yellow oral solution.
HALOCUR contains 0.5 mg/ml halofuginone base (as lactate salt).

4. INDICATION(S)

Prevention of diarrhoea due to diagnosed *Cryptosporidium parvum*, in farms with history ofcryptosporidiosis.
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 case of diarrhoea established for more than 24 hours and in weak animals.

6. ADVERSE REACTIONS

An increase in the level of diarrhoea has been observed in treated animals in very rare

cases. 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.

7. TARGET SPECIES

New born 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 base / kg body weight (BW) / once a day for 7 consecutive days, i.e. 2 ml of HALOCUR / 10 kg BW / once a day for 7 consecutive days.

However, in order to make the HALOCUR treatment easier, a simplified dosage scheme is proposed:

- 35 kg < calves ≤ 45 kg: 8 ml of HALOCUR once a day during 7 consecutive days
- 45 kg < calves < 60 kg: 12 ml of HALOCUR once a day during 7 consecutive days

For smaller or higher weights, a precise calculation should be performed (2 ml/10 kg BW).

9. ADVICE ON CORRECT ADMINISTRATION

To ensure a correct dosage, the use of either a syringe or any appropriate device for oral administration is necessary.

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.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 13 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

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 either a syringe or any appropriate device for oral administration. Do not use 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 the veterinary medicinal product to animals:

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 and eye 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 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.

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

Medicines should not be disposed of via wastewater.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.
HALOCUR should not enter water courses as this may be dangerous for fish and other aquatic organisms.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

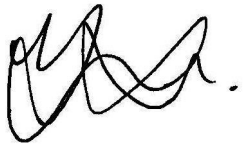
16 August 2019

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. OTHER INFORMATION

High-density polyethylene portable bottle of 500 ml containing 490 ml of the oral solution.
High-density polyethylene portable bottle of 1000 ml containing 980 ml of the oral solution.

Not all pack sizes may be marketed.



Approved: 26 July 2022