

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE – HDPE bottle**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

HALOCUR 0.5 mg/ml oral solution for calves

**2. STATEMENT OF ACTIVE SUBSTANCES**

Halofuginone base            0.5 mg/ml  
(as lactate salt)

**3. PACKAGE SIZE**

500 ml  
1000 ml

**4. TARGET SPECIES**

Cattle (newborn calf).

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

Oral use.

**7. WITHDRAWAL PERIODS**

Withdrawal period: Meat and offal: 13 days.

**8. EXPIRY DATE**

Exp. {mm/yyyy}  
Once broached use within 6 months.

**9. SPECIAL STORAGE PRECAUTIONS**

This veterinary medicinal product does not require any special storage conditions.

**10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

**11. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**13. NAME OF THE MARKETING AUTHORISATION HOLDER**

MSD Animal Health UK Limited.

**14. MARKETING AUTHORISATION NUMBERS**

Vm 01708/5037

**15. BATCH NUMBER**

Lot {number}

## **PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:**

### **PACKAGE LEAFLET**

#### **1. Name of the veterinary medicinal product**

HALOCUR 0.5 mg/ml oral solution for calves

#### **2. Composition**

Each ml contains:

##### **Active substance:**

Halofuginone base (as lactate salt)      0.5 mg

##### **Excipients:**

Benzoic acid (E210)                      1.00 mg

Tartrazine (E102)                         0.03 mg

The veterinary medicinal product is a canary yellow solution.

#### **3. Target species**

Cattle (newborn calf).

#### **4. Indications for use**

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 case 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 excipients.

#### **6. Special warnings**

##### Special warnings:

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure 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 precautions for safe use in the target species:

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 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 spillage onto skin or eye contact wash the exposed area thoroughly with clean water. If eye irritation persists, seek medical advice immediately and show the package leaflet or the label to the physician.

Wash hands after use.

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.

## 7. Adverse events

Cattle (newborn calf):

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

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at Website:

<https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: [adverse.events@vmd.gov.uk](mailto:adverse.events@vmd.gov.uk).

## 8. Dosage for each species, routes and method of administration

Oral use.

To be administered after feeding.

The dosage is: 100 mcg of halofuginone base / kg body weight (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.

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

- 35 kg < calves ≤ 45 kg: 8 ml of the veterinary medicinal product once a day during 7 consecutive days
- 45 kg < calves < 60 kg: 12 ml of the veterinary medicinal product 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**

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 suitably calibrated measuring equipment is recommended.

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 *Cryptosporidium parvum* persists.

## **10. Withdrawal periods**

Meat and offal: 13 days.

## **11. Special storage precautions**

Keep out of the sight and reach of children.  
This veterinary medicinal product does not require any special storage conditions.

Shelf-life after first opening the bottle: 6 months.

## **12. Special precautions for disposal**

Medicines should not be disposed of via wastewater.  
This veterinary medicinal product should not enter water courses as halofuginone may be dangerous for fish and other aquatic organisms.  
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.  
Ask your veterinary surgeon how to dispose of medicines no longer required.

## **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

## **14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES**

Vm 01708/5037

500 ml bottle containing 490 ml of oral solution.

1000 ml bottle containing 980 ml of oral solution.

Not all pack sizes may be marketed.

#### **15. PID LINK (Do not print heading)**

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

#### **16. Contact details**

Marketing authorisation holder and contact details to report suspected adverse reactions:

MSD Animal Health UK Limited.

Walton Manor, Walton

Milton Keynes

MK7 7AJ, UK

Tel.: +44 (0)1908 685685

Manufacturer responsible for batch release:

Intervet Productions S.A.

Rue de Lyons

27460 Igoville

France

#### **17. Other information**

POM-V Veterinary medicinal product subject to prescription.

*Gavin Hall*

Approved: 27 August 2025