SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

STENOROL CRYPTO 0.5 mg/ml oral solution for calves

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Halofuginone (as lactate) 0.50 mg
Equivalent to 0.6086 mg of halofuginone lactate

Excipients:

Quantitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Benzoic acid (E 210)	1.00 mg
Tartrazine (E 102)	0.03 mg
Lactic acid (E270)	
Water for injections	

Clear intensively greenish yellow liquid.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (Newborn calves).

3.2 Indications for use for each target species

In newborn calves:

- 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 diarrhea 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.

3.3 Contraindications

Do not use on an empty stomach.
Do not use in case of diarrhea 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.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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
This veterinary medicinal product contains halofuginone, which can cause allergic reactions in some people. People with known hypersensitivity (allergy) to halofuginone or any of the excipients should administer the veterinary medicinal product with caution. Repetitive contact with the product may lead to skin allergies.
The veterinary medicinal product may be irritating to the skin and eyes and systemic toxicity cannot be excluded in case of contact with the skin.
Avoid skin, eye or mucosal contact with the veterinary medicinal product.
Personal protective equipment consisting of protective gloves should be worn when handling the veterinary medicinal product.
Wash hands after use.
In case of skin and eye contact wash the exposed area thoroughly with clean water. If you develop symptoms following exposure, such as skin rash or eye irritation, you should seek medical advice and show the physician this warning. Swelling of the face, lips and eyes or difficulty in breathing are more serious symptoms and require urgent medical attention.

Special precautions for the protection of the environment:
Not applicable.

Other precautions:
Not applicable.

3.6 Adverse events

Newborn calves:

Very rare (< 1 animal / 10,000 animals treated, including isolated reports)	Diarrhoea[1]

[1]Increase of the level.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Not applicable.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

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.
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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and 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 should be stopped immediately and the animal fed unmedicated milk or milk replacer. Rehydration may be necessary.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: 13 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP51AX08

4.2 Pharmacodynamics

The active substance, Halofuginone, is an antiprotozoal agent of the quinazolinone derivate group (nitrogenous polyheterocycles). Halofuginone lactate is a salt whose antiprotozoal properties and activity against Cryptosporidium parvum have been demonstrated both in in vitro conditions and in artificial and natural infections. The compound has a cryptosporidiostatic effect on Cryptosporidium parvum. It is mainly active on the free stages of the parasite (sporozoite, merozoite). The concentrations to inhibit 50% and 90% of the parasites, in an in vitro test system, are IC50 < 0.1 µg/ml and IC90 of 4.5 µg/ml respectively.

4.3 Pharmacokinetics

The bioavailability of the drug in the calf, following single oral administration, is about 80%. The time necessary to obtain the maximum concentration Tmax is 11 hours. The maximum concentration in plasma Cmax is 4 ng/ml. The apparent volume of distribution is 10 l/kg. The plasmatic concentrations of halofuginone after repeated oral administrations are comparable to the pharmacokinetic pattern after single oral treatment. Unchanged halofuginone is the major component in the tissues. Highest values have been found in the liver and the kidney. The veterinary medicinal product is mainly excreted in the urine. The terminal elimination half-life is 11.7 hours after IV administration and 30.84 hours after single oral administration.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf-life of the veterinary medicinal product as a packaged for sale: 2 years.
Shelf-life after first opening of the immediate packaging: 6 months.

5.3 Special precautions for storage

Do not store above 25°C. Store in the original container in order to protect from light.

5.4 Nature and composition of immediate packaging

White high density polyethylene bottle with tamper-evident screw polypropylene closure.

Pack sizes:
Bottle of 500 mL
Bottle of 1 L

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as halofuginone lactate 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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV

7. MARKETING AUTHORISATION NUMBER

Vm 30282/5020

8. DATE OF FIRST AUTHORISATION

23 July 2020

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

July 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

Gavin Hall
Approved: 10 December 2024