

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 (E 270)	
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 veterinary medicinal 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.

3.6 Adverse events

Newborn calves:

Very rare (< 1 animal / 10,000 animals treated, including isolated reports)	Diarrhoea ¹
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¹Increase 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 its local representative 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

Oral use.

To be administered 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 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 $IC_{50} < 0.1 \mu\text{g/ml}$ and IC_{90} of $4.5 \mu\text{g/ml}$ 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 T_{max} is 11 hours. The maximum concentration in plasma C_{max} 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 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 watercourses, 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(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:

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

CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database](https://medicines.health.europa.eu/veterinary) (<https://medicines.health.europa.eu/veterinary>).

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**HDPE Bottle****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

STENOROL CRYPTO 0.5 mg/ml oral solution for calves

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Halofuginone (as lactate) 0.50 mg

Equivalent to 0.6086 mg of halofuginone lactate

3. PACKAGE SIZE

500 ml

1 L**4. TARGET SPECIES**

Cattle (Newborn calves).

5. INDICATIONS**6. ROUTES OF ADMINISTRATION**

Oral use.

7. WITHDRAWAL PERIODS

Withdrawal period:

Meat and offal: 13 days.

8. EXPIRY DATE

Exp:

Once broached use by....

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

9. SPECIAL STORAGE PRECAUTIONS

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

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”
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Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV

14. MARKETING AUTHORISATION NUMBERS
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15. BATCH NUMBER

Lot:

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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2. Composition

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Excipients:

Benzoic acid (E 210) 1 mg

Tartrazine (E 102) 0.03 mg

Clear intensively greenish-yellow liquid.

3. Target species

Cattle (Newborn calves).

4. Indications for use

In newborn calves:

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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.

5. 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.

6. Special warnings

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. Do not use on an empty stomach. 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.

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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.

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 should be stopped immediately and the animal fed unmedicated milk or milk replacer. Rehydration may be necessary.

Major incompatibilities:

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

7. Adverse events

Cattle:

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

¹Increase of the level.

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 <or the local representative of the authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

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

Oral use.

To be administered in calves after feeding.

The dosage is: 100 µg of halofuginone base /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.

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 periods

Meat and offal: 13 days.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25°C. Store in the original container 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 immediate packaging: 6 months.

12. Special precautions for disposal

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

The veterinary medicinal product should not enter watercourses, 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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist 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

500 mL bottle

1 L bottle

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder:

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerpen
Belgium
+32 3 288 18 49
pharmacovigilance@huvepharma.com

Manufacturer responsible for batch release:

Biovet JSC
39 Petar Rakov Str
4550 Peshtera
Bulgaria

Local representative and contact details to report suspected adverse reactions: