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

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral solution.
Clear liquid of intense greenish-yellow coloration.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle (Newborn calves)

4.2 Indications for use, specifying the 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.

4.3 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.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

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 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 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 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 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.

4.6 Adverse reactions (frequency and seriousness)

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).

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

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 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Meat and offal: 13 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiprotozoals, Agents against protozoal disease.
ATC vet code: QP51AX08

5.1 Pharmacodynamic properties

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 mg/ml and IC_{90} of 4.5 mg/ml respectively.

5.2 Pharmacokinetic particulars

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 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzoic acid (E 210)
Tartrazine (E 102)
Lactic acid (E270)
Water for injections

6.2 Major incompatibilities

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

6.3 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 month.

6.4 Special precautions for storage

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

6.5 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.

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

The product should not enter watercourses, as this may be dangerous for fish and other aquatic organisms. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with the local requirements.

7 MARKETING AUTHORISATION HOLDER

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerpen
Belgium

8 MARKETING AUTHORISATION NUMBER(S)

VPA10782/036/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24th July 2020

10 DATE OF REVISION OF THE TEXT

June 2021