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
Halofuginone as lactate

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Halofuginone (as lactate) 0.50 mg
Equivalent to 0.6086 mg of halofuginone lactate

3. PHARMACEUTICAL FORM

Oral solution.

4. PACKAGE SIZE

500 ml
1 L

5. TARGET SPECIES

Cattle (Newborn calves).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use in 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:

Once broached use by….

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

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

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

Huvepharma N.V.
Uitbreidingstraat 80
B-2600 Antwerpen
Belgium

16. MARKETING AUTHORISATION NUMBER(S)

Vm 30282/4044

17. MANUFACTURER'S BATCH NUMBER

Lot:

B. PACKAGE LEAFLET

PACKAGE LEAFLET
STENOROL CRYPTO 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:

Huvepharma N.V.
Uitbreidingstraat 80
B-2600 Antwerpen
Belgium

Manufacturer responsible for batch release:

Biovet JSC
39 Petar Rakov Str
4550 Peshtera
Bulgaria

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

STENOROL CRYPTO 0.5 mg/ml oral solution for calves
Halofuginone (as lactate)

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains:
Active substance: halofuginone (as lactate) 0.50 mg
Equivalent to 0.6086 mg of halofuginone lactate

Excipients:
Benzoic acid (E210) 1 mg
Tartrazine (E102) 0.03 mg

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

4. INDICATION(S)

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.

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. ADVERSE REACTIONS

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).

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.
Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Cattle (Newborn 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 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.

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.

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 container: 6 months.

12. SPECIAL WARNING(S)

Special warnings for each target species:

None.

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. 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

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.

Pregnancy and lactation:

Not applicable.

Interaction with other medicinal products and other forms of interaction:

None known.

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

Incompatibilities:

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

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

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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

April 2021

15. OTHER INFORMATION

White high density polyethylene bottle of 500 ml and 1 L with tamper-evident screw polypropylene closure.
Not all pack sizes may be marketed.

Approved: 15/06/21