

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HALAGON 0.5 mg/ml oral solution for calves

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Halofuginone (as lactate salt) 0.50 mg
Equivalent to 0.6086 mg of halofuginone lactate

Excipients:

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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral solution.

Clear yellow solution.

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* infection, 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* infection.
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. An appropriate device for oral administration is included. For treatment of anorexic calves, the product should be administered in half a liter 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

People with known hypersensitivity to the active substance or any of the excipients should administer the veterinary medicinal product with caution.

Repetitive contact with the product may lead to skin allergies.

Avoid skin, eye or mucosal contact with the product. Wear protective gloves while handling the product. In case of skin and eye contact wash the exposed area thoroughly with clean water. If eye irritation persists, seek medical advice.

Wash hands after use.

4.6. Adverse reactions (frequency and seriousness)

An increase in the level of diarrhoea has been observed in very rare cases 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 interaction

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 body weight (bw) / once a day for 7 consecutive days, i.e. 4 ml of HALAGON / 20 kg bw / once a day for 7 consecutive days.

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

- 35 kg < calves ≤ 45 kg: 8 ml of HALAGON once a day during 7 consecutive days
- 45 kg < calves < 60 kg: 12 ml of HALAGON once a day during 7 consecutive days

For smaller or higher weights, a precise calculation should be performed (4 ml/20 kg).

To ensure a correct dosage, an appropriate metering pump for administration of 'HALAGON' is included.

- 1) Screw the metering pump on the bottle.
- 2) Remove the protector cap from the nozzle.
- 3) If the metering pump is used for the first time (or hasn't been used for a few days), carefully pump till a drop of solution is formed on top of the nozzle.

- 4) Restrain the calf and insert the nozzle of the metering pump into the calves mouth.
- 5) Pull the trigger of the metering pump completely for release of a dose that equals 4 ml of solution. Pull twice or three times, respectively, for administration of the desired volume (8 ml for calves of 35 – 45 kg and 12 ml for calves of 45 – 60 kg, respectively).
- 6) Put the protector cap back on the nozzle.

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 must 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 PROPERTIES

Pharmacotherapeutic group: Other antiprotozoal agents, halofuginone.

ATCvet code: QP51AX08.

5.1. Pharmacodynamic properties

The active substance, halofuginone, is an antiprotozoal agent of the quinazolinone derivatives group (nitrogenous polyheterocycles). Halofuginone lactate is a salt whose antiprotozoal properties and efficacy 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 (sporozoïte, merozoïte). 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.

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 (E210)

Lactic acid (E270)

Tartrazine (E102)

Water, purified

6.2. Major incompatibilities

Not applicable.

6.3. Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years

Shelf-life after first opening the immediate packaging: 6 months.

6.4. Special precautions for storage

Keep the bottle in the outer carton in order to protect from light.

6.5. Nature and composition of immediate packaging

- Cardboard box containing one bottle (high-density polyethylene) of 290 ml oral solution.
- Cardboard box containing one bottle (high-density polyethylene) of 490 ml oral solution.
- Cardboard box containing one bottle (high-density polyethylene) of 980 ml oral solution.

Each bottle is sealed with a polypropylene cap.

Each package also contains a 4 ml metering pump that consists of several components made out of high, low and linear low-density polyethylene, polypropylene, stainless steel and silicone.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

The product should not enter watercourses as this may be dangerous for fish and other aquatic organisms.

7. MARKETING AUTHORISATION HOLDER

EMDOKA bvba
J. Lijsenstraat 16
B-2321 Hoogstraten
Belgium

8. MARKETING AUTHORISATION NUMBERS

EU/2/16/201/001

EU/2/16/201/002

EU/2/16/201/003

9. DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13/12/2016

Date of last renewal:

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency <http://www.ema.europa.eu/>.

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

- A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OF RESTRICTIONS REGARDING SUPPLY OR USE**
- C. STATEMENT OF THE MRLs**

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Divasa-Farmavic, S.A.
Ctra. Sant Hipolit, Km. 71
08503 Gurb-Vic, Barcelona
Spain

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

The active substance in HALAGON is an allowed substance as described in table 1 of the annex to Commission Regulation (EU) No 37/2010:

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Halofuginone	Halofuginone	Bovine	10 µg/kg 25 µg/kg 30 µg/kg 30 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption	Antiparasitic agents/Agents acting against protozoa

The excipients listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or are considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Outer carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HALAGON 0.5 mg/ml oral solution
halofuginone

2. STATEMENT OF ACTIVE SUBSTANCES

Halofuginone (as lactate salt) 0.50 mg/ml

3. PHARMACEUTICAL FORM

Oral solution

4. PACKAGE SIZE

1 cardboardbox containing 1 x 290 ml
1 cardboardbox containing 1 x 490 ml
1 cardboardbox containing 1 x 980 ml

5. TARGET SPECIES

Cattle (newborn calves)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): meat and offal: 13 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP

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

Once broached, use by ...

11. SPECIAL STORAGE CONDITIONS

Keep the bottle in the outer carton in order to protect from light.

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

Disposal: read package leaflet.

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

EMDOKA bvba
John Lijsenstraat 16
B-2321 Hoogstraten
Belgium

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/16/201/001 (290 ml)

EU/2/16/201/002 (490 ml)

EU/2/16/201/003(980 ml)

17. MANUFACTURER’S BATCH NUMBER

Batch

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle of 290ml, 490 ml or 980 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HALAGON 0.5 mg/ml oral solution
halofuginone

2. STATEMENT OF ACTIVE SUBSTANCES

Halofuginone (as lactate salt) 0.50 mg/ml

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

1 cardboardbox containing 1 x 290 ml
1 cardboardbox containing 1 x 490 ml
1 cardboardbox containing 1 x 980 ml

5. TARGET SPECIES

Cattle (newborn calves)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): meat and offal: 13 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP

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

Once broached, use by ...

11. SPECIAL STORAGE CONDITIONS

Keep the bottle in the outer carton in order to protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE AMTERIALS, IF ANY**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”**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

EMDOKA bvba
John Lijssenstraat 16
B-2321 Hoogstraten
Belgium

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/16/201/001 (290 ml)

EU/2/16/201/002 (490 ml)

EU/2/16/201/003 (980 ml)

17. MANUFACTURER’S BATCH NUMBER

Batch

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

HALAGON 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:

EMDOKA bvba
John Lijssenstraat 16
B-2321 Hoogstraten
Belgium

Manufacturer responsible for batch release:

Divasa-Farmavic, S.A.
Ctra. Sant Hipolit, Km. 71
08503 Gurb-Vic, Barcelona
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

HALAGON 0.5 mg/ml oral solution for calves
halofuginone (as lactate salt)

3. STATEMENT OF ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Each ml contains:

Active substance:

Halofuginone (as lactate salt) 0.50 mg
Equivalent to 0.6086 mg of halofuginone lactate

Excipients:

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

Clear yellow oral solution.

4. INDICATION(S)

In new-born calves:

- Prevention of diarrhoea due to diagnosed *Cryptosporidium parvum* infection, 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* infection.
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. ADVERSE REACTIONS

An increase in the level of diarrhoea has been observed in very rare cases 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.

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 / kg body weight (bw) / once a day for 7 consecutive days, i.e. 4 ml of HALAGON / 20 kg bw / once a day for 7 consecutive days.

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

- 35 kg < calves ≤ 45 kg: 8 ml of HALAGON once a day during 7 consecutive days
- 45 kg < calves < 60 kg: 12 ml of HALAGON once a day during 7 consecutive days

For smaller or higher weights, a precise calculation should be performed (4 ml/20 kg).

To ensure a correct dosage, an appropriate doser for administration of 'HALAGON' is included.

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.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure a correct dosage, an appropriate doser for administration of 'HALAGON' is included.

- 1) Screw the metering pump on the bottle.
- 2) Remove the protector cap from the nozzle.
- 3) If the metering pump is used for the first time (or hasn't been used for a few days), carefully pump till a drop of solution is formed on top of the nozzle.
- 4) Restrain the calf and insert the nozzle of the metering pump into the calves mouth.

- 5) Pull the trigger of the metering pump completely for release of a dose that equals 4 ml of solution. Pull twice or three times, respectively, for administration of the desired volume (8 ml for calves of 35 – 45 kg and 12 ml for calves of 45 – 60 kg, respectively).
- 6) Put the protector cap back on the nozzle.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 13 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Keep the bottle in the outer carton 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.

Shelf-life after first opening the immediate packaging: 6 months.

12. SPECIAL WARNING(S)

Special precautions for use in animals:

Administer after colostrum feeding, or after milk or milk replacer feeding only. An appropriate device for oral administration is included. 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:

People with known hypersensitivity to the active substance or any of the excipients should administer the veterinary medicinal product with caution.

Repetitive contact with the product may lead to skin allergies.

Avoid skin, eye or mucosal contact with the product. Wear protective gloves while handling the product. In case of skin and eye contact wash the exposed area thoroughly with clean water. If eye irritation persists, seek medical advice.

Wash hands after use.

Pregnancy and lactation:

Not applicable.

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

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

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

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency <http://www.ema.europa.eu/>.

15. OTHER INFORMATION

- Cardboard box containing one bottle (high-density polyethylene) of 290 ml oral solution.
- Cardboard box containing one bottle (high-density polyethylene) of 490 ml oral solution.
- Cardboard box containing one bottle (high-density polyethylene) of 980 ml oral solution.

Not all pack sizes may be marketed.

To be supplied only on veterinary prescription.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

België/Belgique/Belgien

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