

[Version 9.1,11/2024]

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cocciril 2.5 mg/ml oral suspension for cattle and sheep (AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FR, HR, HU, IE, IT, LT, LV, LU, MT, NL, PL, PT, RO, SI, SK).

Cocciril vet 2.5 mg/ml oral suspension for cattle and sheep (FI, NO, SE).

Dicla-cocci 2.5 mg/ml oral suspension for cattle and sheep (UK(NI)).

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:

Active substances:

Diclazuril 2.5 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Methyl parahydroxybenzoate (E218)	1.8 mg
Propyl parahydroxybenzoate	0.2 mg
Microcrystalline cellulose and carmellose sodium	
Citric acid	
Sodium hydroxide	
Polysorbate 20	
Water for injections	

White suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (calves) and sheep (lambs).

3.2 Indications for use for each target species

Cattle (calves):

Prophylaxis of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii*.

Sheep (lambs):

Prophylaxis of coccidiosis caused by *Eimeria crandallis* and *Eimeria ovinoidalis*.

Use the veterinary medicinal product during the prepatent period of infection for the prevention of clinical signs.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipient(s).

3.4 Special warnings

Calves:

In certain cases, only a transient reduction of oocyst shedding may be achieved.

If there is no recent and confirmed history of clinical coccidiosis, the presence of the disease in the flock or herd should be confirmed by faecal sampling prior to treatment.

The preferred timing of treatment is directed by the known epidemiology of *Eimeria spp.* with treatment being most effective during the pre-patent phase of the infection before clinical signs occur.

Coccidiosis is an indicator of insufficient hygiene in the flock/pen. It is recommended to improve hygiene and to treat all calves in a pen and all lambs in a group. This will contribute to reduce the infection pressure and assure a better epidemiological control of the coccidiosis infection.

Repeated use for an extended period, particularly when using the same class of substances, increases the risk of resistance development. The decision to use the product should be based on confirmation of the coccidian species and burden, or of the risk of infection based on its epidemiological features, for each herd/flock.

Unnecessary use of antiprotozoals or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy.

Cross-resistance between toltrazuril and diclazuril is possible and should be investigated. Use of diclazuril should be carefully considered when susceptibility testing has shown resistance to triazine-derivates because its effectiveness may be reduced.

It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method (e.g. faecal oocyst count reduction test). Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities. If resistance is present, it should be considered to use an antiprotozoal from another class/with a different mechanism of action.

Therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.

Use of the product should be in accordance with official, national and regional antimicrobial policies.

To alter the course of an established clinical coccidial infection, in individual animals already showing signs of diarrhoea, additional supportive therapy is required.

3.5 Special precautions for use

Special precautions for safe use in the target species:

This veterinary medicinal product should only be used in a restricted number of animals at high risk of infection, i.e. animals kept in the same restricted, contaminated environment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Esters of parahydroxybenzoic acid may cause allergic reactions (possibly delayed). People with known hypersensitivity to parabens should administer the veterinary medicinal product with caution.

Wash hands after administration of the veterinary medicinal product.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle (calves) and sheep (lambs):

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Gastrointestinal signs (e.g. Diarrhea ^{1,2}); Lethargy, Recumbency; Agitation; Neurological signs (e.g. Paresis)
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¹: with possible presence of blood

²: even though oocyst excretion is reduced to a very low 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.

Oral suspension to be administered at a dosage of 1 mg diclazuril per kg body weight i.e. 1 mL per 2.5 kg body weight in a single oral administration.

To ensure a correct dosage, body weight should be determined as accurately as possible.

Underdosing could result in ineffective use and may favour resistance development.

Method of administration:

Shake vigorously for 1 minute by repeatedly turning the bottle upside down by wrist action.

For the 5 L and 2.5 L back-pack bottles, use a drenching gun. Connect the drenching gun and draw-off tubing to the back-pack bottle as follows:

- Attach the open end of the draw-off tubing to an appropriate drenching gun.
- Attach draw-off tubing to the spigot cap that is included in the pack.
- Replace shipping cap with the spigot cap having the draw-off tubing. Tighten the spigot cap.
- Gently prime the drenching gun, checking for leaks.
- Follow the drenching gun manufacturer's directions for adjusting the dose and proper use and maintenance of the drenching gun and draw-off tubing.
- After using spigot cap, re-close container with the shipping cap.

For the 1L and 250 mL bottles, to ensure a correct dosage, the use of either a syringe or an appropriate device for oral administration is necessary and the veterinary medicinal product should be administered directly in the mouth of the animal.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Cattle (calves):

No signs of overdose were noted after a single administration of 5 times the recommended dose. In case of repeated administration of 3 to 5 times the dose, on 3 consecutive days, a softening and a

colour change (dark brown) of the faeces can be observed in some calves. These observations were transient and disappeared without specific treatment.

Sheep (lambs):

No signs of overdose were noted after administration of 5 times the recommended dose.

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

Cattle (calves) and sheep (lambs):

Meat and offal: zero days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QP51BC03

4.2 Pharmacodynamics

Diclazuril is an anticoccidial of the benzeneacetonitrile group without antibacterial activity and has anticoccidial activity against *Eimeria* species. Depending on the coccidia species, diclazuril has a coccidiocidal effect on the asexual or sexual stages of the development cycle of the parasite. Diclazuril treatment will only have limited effect on the intestinal lesions caused by parasitic stages older than 16 days. Treatment with diclazuril causes interruption of the coccidial cycle and of excretion of oocysts for approximately 2 weeks. This allows the animal to bridge the period of decrease of maternal immunity (observed at approximately 4 weeks of age).

4.3 Pharmacokinetics

The absorption of diclazuril in lambs is poor after administration of the oral suspension. Maximum concentrations in plasma are reached about 24 hours after dosing. The absorption decreases with the animals' age. The elimination half-life is about 30 hours. *In-vitro* studies on sheep hepatocytes demonstrated that metabolic transformation of diclazuril is limited. This was equally observed in other animal species. Excretion occurs almost completely via the faeces.

When diclazuril is administered in oral suspension to calves, its absorption is poor.

Environmental properties

Diclazuril has been shown to be very persistent in soil.

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 packaged for sale: 3 years.

Shelf life after first opening the immediate packaging: 3 months.

5.3 Special precautions for storage

Do not freeze. Protect from frost.

5.4 Nature and composition of immediate packaging

The veterinary medicinal product is packed in four container types:

- White, high-density polyethylene hanging bottle of 250 mL closed with black screw closure made of polypropylene with a polyethylene-lined sealing disk (wadding) for induction sealing inside. One 250 mL bottle per cardboard box together with a spigot cap.
- White, high-density polyethylene back-pack bottle of 1 L closed with black screw closure made of polypropylene with a polyethylene-lined sealing disk (wadding) for induction sealing inside. One 1 L back-pack bottle per cardboard box together with a spigot cap and back-pack strap.
- White, high-density polyethylene back-pack bottle of 2.5 L closed with black screw closure made of polypropylene with a polyethylene-lined sealing disk (wadding) for induction sealing inside. One 2.5 L back-pack bottle per cardboard box together with a spigot cap and back-pack strap.
- White, high-density polyethylene back-pack bottle of 5 L closed with black screw closure made of polypropylene with a polyethylene-lined sealing disk (wadding) for induction sealing inside. One 5 L back-pack bottle per cardboard box together with a spigot cap and back-pack strap.

Not all pack sizes may be marketed.

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

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

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: {DD/MM/YYYY}.

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

{MM/YYYY}

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).

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cocciril 2.5 mg/ml oral suspension

2. STATEMENT OF ACTIVE SUBSTANCE

One ml contains:

Active substances:

Diclazuril 2.5 mg

3. PACKAGE SIZE

250 mL

1 L

2.5 L

5 L

4. TARGET SPECIES

Cattle (calves) and sheep (lambs).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle (calves) and sheep (lambs):

Meat and offal: zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 3 months.

Once opened use by.....

9. SPECIAL STORAGE PRECAUTIONS

Do not freeze.

Protect from frost.

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”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV

14. MARKETING AUTHORISATION NUMBER

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

HDPE BOTTLE 250 mL - 1 L – 2.5 L - 5 L

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cocciril 2.5 mg/ml oral suspension

2. STATEMENT OF ACTIVE SUBSTANCES

One ml contains:

Active substances:

Diclazuril 2.5 mg

3. TARGET SPECIES

Cattle (calves) and sheep (lambs).

4. ROUTES OF ADMINISTRATION

Oral use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle (calves) and sheep (lambs):

Meat and offal: zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 3 months.

Once opened use by....

7. SPECIAL STORAGE PRECAUTIONS

Do not freeze.

Protect from frost.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

Repeated use for an extended period, particularly when using the same class of substances, increases the risk of resistance development. The decision to use the product should be based on confirmation of the coccidian species and burden, or of the risk of infection based on its epidemiological features, for each herd/flock.

Unnecessary use of antiprotozoals or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy.

Cross-resistance between toltrazuril and diclazuril is possible and should be investigated. Use of diclazuril should be carefully considered when susceptibility testing has shown resistance to triazine-derivates because its effectiveness may be reduced.

It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method (e.g. faecal oocyst count reduction test). Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities. If resistance is present, it should be considered to use an antiprotozoal from another class/with a different mechanism of action.

Therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.

Use of the product should be in accordance with official, national and regional antimicrobial policies.

To alter the course of an established clinical coccidial infection, in individual animals already showing signs of diarrhoea, additional supportive therapy is required.

Special precautions for safe use in the target species:

This veterinary medicinal product should only be used in a restricted number of animals at high risk of infection, i.e. animals kept in the same restricted, contaminated environment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Esters of parahydroxybenzoic acid may cause allergic reactions (possibly delayed). People with known hypersensitivity to parabens should administer the veterinary medicinal product with caution.

Wash hands after administration of the veterinary medicinal product.

Pregnancy, lactation, lay:

Not applicable.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose:

Cattle (calves):

No signs of overdose were noted after a single administration of 5 times the recommended dose. In case of repeated administration of 3 to 5 times the dose, on 3 consecutive days, a softening and a colour change (dark brown) of the faeces can be observed in some calves. These observations were transient and disappeared without specific treatment.

Sheep (lambs):

No signs of overdose were noted after administration of 5 times the recommended dose.

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 (calves) and sheep (lambs):

Very rare (<1 animal / 10 000 animals treated, including isolated reports):
Gastrointestinal signs (e.g. Diarrhea ^{1,2})
Lethargy, Recumbency
Agitation
Neurological signs (e.g. Paresis)

¹: with possible presence of blood

²: even though oocyst excretion is reduced to a very low 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 its local representative 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.

Oral suspension to be administered at a dosage of 1 mg diclazuril per kg body weight i.e. 1 mL per 2.5 kg body weight in a single oral administration.

9. Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible.

Underdosing could result in ineffective use and may favour resistance development.

Method of administration:

Shake vigorously for 1 minute by repeatedly turning the bottle upside down by wrist action.

For the 5 L and 2.5 L back-pack bottles, use a drenching gun. Connect the drenching gun and draw-off tubing to the back-pack bottle as follows:

- Attach the open end of the draw-off tubing to an appropriate drenching gun.
- Attach draw-off tubing to the spigot cap that is included in the pack.
- Replace shipping cap with the spigot cap having the draw-off tubing. Tighten the spigot cap.
- Gently prime the drenching gun, checking for leaks.
- Follow the drenching gun manufacturer's directions for adjusting the dose and proper use and maintenance of the drenching gun and draw-off tubing.
- After using spigot cap, re-close container with the shipping cap.

For the 1L and 250 mL bottles, to ensure a correct dosage, the use of either a syringe or an appropriate device for oral administration is necessary and the veterinary medicinal product should be administered directly in the mouth of the animal.

10. Withdrawal periods

Cattle (calves) and sheep (lambs):

Meat and offal: zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not freeze.

Protect from frost.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the bottle after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 3 months.

12. Special precautions for disposal

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

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

Pack sizes:

- Cardboard box with one 250 mL hanging bottle and spigot cap.
- Cardboard box with one 1 L back-pack bottle, spigot cap and back-pack-strap.
- Cardboard box with one 2.5 L back-pack bottle, spigot cap and back-pack-strap.
- Cardboard box with one 5 L back-pack bottle, spigot cap and back-pack strap.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

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 <and contact details to report suspected adverse events>:

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerpen
Belgium
<Tel: +32 3 288 18 49>

Manufacturer responsible for batch release:

Biovet JSC
39 Petar Rakov Str
4550 Peshtera
Bulgaria

<Local representatives and contact details to report suspected adverse events:>

<17. Other information>

Diclazuril has been shown to be very persistent in soil.

