

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 NUMBERS

Vm 30282/3021 – UK(NI)

Vm 30282/5019 – UK(GB)

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

Dicla-cocci 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}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Dicla-cocci 2.5 mg/ml oral suspension for cattle and sheep.

2. Composition

One ml contains:

Active substances:

Diclazuril 2.5 mg

Excipients:

Methyl parahydroxybenzoate (E218) 1.8 mg

Propyl parahydroxybenzoate 0.2 mg

White suspension.

3. Target species

Cattle (calves) and sheep (lambs).

4. Indications for use

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.

5. Contraindications

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

6. Special warnings

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.

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 at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

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.

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

Vm 30282/3021 – UK(NI)

Vm 30282/5019 – UK(GB)

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. PID link (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse events:

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerp
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:

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

17. Other information

Diclazuril has been shown to be very persistent in soil.

POM-VPS

Gavin Hall

Approved: 16 December 2025