

Veterinary product package leaflet

This medicine is dispensed according to veterinarian's prescription only
For use in animals only

1. Name, form and strength of the veterinary medicine

Vecoxan® Veterinary
2.5 mg/ml oral suspension

2. Active ingredient

Each 1 ml contains Diclazuril 2.5 mg.

The list of inactive ingredients in the product appears in section 13 'Additional information'.

3. What is this medicine intended for?

For the prevention of coccidiosis due to *Eimeria crandallis* and *Eimeria ovinoidalis* in lambs.

Prevention of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii* in calves.

If there is no recent history of clinical coccidiosis in the herd, examination of the presence of coccidia in the feces should be performed before treatment is started.

Therapeutic group:
antiprotozoal, triazines

4. Contraindications

Do not use in cases of hypersensitivity to the active ingredient or to any of the inactive ingredients.

5. Side effects

In very rare cases, side effects associated with gastrointestinal disorders (such as diarrhea, with possible presence of blood), lethargy and/or neurological disorders (agitation, decubitus, paresis, etc.) have been reported.

Some treated animals may show signs of clinical disease (diarrhea), even if oocyst excretion is reduced to a very low level.

The frequency of side effects is defined as follows:

- very common (effects that appear in more than 1 in 10 animals treated)
- common (effects that appear in more than 1 but less than 10 in 100 animals treated)
- uncommon (effects that appear in more than 1 but less than 10 in 1,000 animals treated)
- rare (effects that appear in more than 1 but less than 10 in 10,000 animals treated)
- very rare (effects that appear in less than 1 in 10,000 animals treated, including isolated reports).

If you notice any serious side effects or any other side effects, even those not already listed in this package leaflet, please inform the veterinarian.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.it) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.it/>

6. Target animals

Sheep (lambs) and cattle (calves).

7. Dosage and method of administration

The dosage is 1 mg Diclazuril per kg of body weight (1 ml Vecoxan® Veterinary per 2.5 kg of body weight) as a single, oral administration, at the age of 4-6 weeks when infestation of the disease is expected to appear. In cases of severe infestation, an additional dose may be needed after 3 weeks.

To ensure correct dosage, the body weight of the animal should be determined as accurately as possible.

8. How to use this product

Shake well before use.

To ensure correct dosage, the body weight of the animal should be determined as accurately as possible.

When animals are to be treated collectively rather than individually, they should be grouped according to body weight and given an appropriate treatment dose to avoid under- or overdosing.

9. Withdrawal period

Meat and offal:

Lambs: zero days

Calves: zero days

10. Warnings

- Special warnings about treating the target animal with this medicine:
Avoid underdosing, which may be related to an underestimation of the animal's weight, improper administration of the product, or lack of calibration of the dosing device (if in use).
In some cases with calves, only a transient reduction in the number of oocysts excreted can be achieved.
Clinical cases of suspected anticoccidial resistance should be further investigated via appropriate testing (e.g., the fecal egg excretion reduction test). If there is a strong suspicion of resistance to a particular anticoccidial medication as a result of testing, an anticoccidial medication from another pharmacological class with a different mechanism of action should be used.
- Special warnings about the safety of using the medicine in animals:
The optimal time of treatment depends on the epidemiological context of coccidiosis in the herd and, in the absence of recent and confirmed cases of clinical coccidiosis, the presence of coccidial infection should be verified by coprological analysis before treatment is started.

Coccidiosis is an indicator of poor hygiene in the herd or pen. It is therefore advisable to improve hygiene and treat all the lambs in the herd and all calves in the pen.

Frequent and repeated use of antiprotozoal drugs can lead to the development of resistance in pathogenic parasites.

To inhibit the development of overt clinical coccidiosis, especially in animals already experiencing diarrhea, additional symptomatic treatment may be necessary. Diclazuril does not have antibacterial activity.

- Special safety precautions for the person administering the product:
Wash hands after administering the product.
- Pregnancy and lactation of the animal treated:
Not applicable
- Overdose:
In lambs: No signs of overdose were observed after administration of 5 times the recommended dose.
In calves: No signs of overdose were observed after administration of 5 times the recommended dose. After repeated administration of 3 to 5 times the dose for 3 consecutive days, softening and a change in color (dark brown) were observed in the feces of certain calves. These effects were transient and disappeared without specific treatment.

11. Storage instructions

Avoid poisoning! To avoid poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants.

Do not use the medicine after the expiry date (exp. date) which appears on the package.

The expiry date refers to the last day of that month.

Store up to 25°C.

Do not freeze. Protect against heat.

Use within 3 months of first opening and no later than the expiry date of the product.

12. Instructions for the disposal of unused product or waste materials of the product at the end of the use

Dispose of any remaining veterinary product or waste obtained from using a veterinary product as toxic waste; do not discard into a sewer.

13. Additional information

- In addition to the active ingredient, this medicine also contains:
Microcrystalline cellulose and carboxymethylcellulose sodium, Methyl parahydroxybenzoate, Citric acid monohydrate, Polysorbate 20, Propyl parahydroxybenzoate, Sodium hydroxide, Purified water
- What the medicine looks like and content of the pack:
Plastic container with 1, 2.5 or 5 liters

Not all pack sizes may be marketed.
- Registration holder's name and address:
Intervet (Israel) Ltd. Neve Ne'eman Industrial Zone, Hod Hasharon 45240
- Manufacturer's name and address:
Lusomedicamenta – Sociedade Technica Farmaceutica, Portugal:
Estrada Consiglieri Pedroso 69-B, Queluz De Baixo, P-2730-055, Barcarena, Portugal

This leaflet was revised in December 2023 according to MOH guidelines.

**Registration number of the product in the Ministry of Health National Drug
Registry: 083-75-92407-00**