[Version 9,03/2022] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vecoxan 2.5 mg/ml Oral Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains

Active substance:
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 monohydrate	
Polysorbate 20	
Sodium hydroxide	
Purified water	

White, oral suspension.

3. CLINICAL INFORMATION

3.1 Target species

Sheep (lambs) and cattle (calves).

3.2 Indications for use for each target species

Sheep (lambs):
Prevention of coccidiosis caused by *Eimeria crandallis* and *Eimeria ovinoidalis*.

Cattle (calves):
Prevention of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii*.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

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

Avoid underdosing, which may be due to underestimation of body weight, misadministration of the product or lack of calibration of the dosing device (if any).
Cattle (calves): in certain cases, only a transient reduction of oocyst shedding may be achieved.
Suspected clinical cases of resistance to anticoccidials should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anticoccidial, an anticoccidial belonging to another pharmacological class and having a different mode of action should be used.

3.5 Special precautions for use

Special precautions for safe use in the target species:
The preferred timing of treatment is directed by the known epidemiology of *Eimeria* spp. and the presence of coccidia in the flock or herd should be confirmed by faecal sampling prior to treatment, if there is no recent and confirmed history of clinical coccidiosis.

Coccidiosis is an indicator of insufficient hygiene in the flock/pen. It is recommended to improve hygiene and to treat all lambs in the flock and all calves in a pen.

Frequent and repeated use of antiprotozoals may lead to the development of resistance in the target parasite.

To alter the course of an established clinical coccidial infection, in individual animals already showing signs of diarrhoea, additional supportive therapy may be required as diclazuril has no antimicrobial activity.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
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. Diarrhoea[1,2]); Lethargy, Recumbency; Agitation; Neurologic signs (e.g. Paresis)

[1] with possible presence of blood.
[2] in some treated animals, 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.

Shake well before use.

Single administration of 1 mg diclazuril per kg body weight (i.e. 1 ml of the oral suspension per 2.5 kg body weight).
To ensure a correct dosage, body weight should be determined as accurately as possible.
If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under - or overdosing

The use of suitably calibrated measuring equipment is recommended.

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

In lambs: no signs of overdose were noted after administration of 5 times the recommended dose.
In 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.

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

Lambs and calves:
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 antimicrobial 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

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.

5.4 Nature and composition of immediate packaging

Nature of the container
HDPE bottle closed with HDPP cap and auxiliary carton box containing HDPP dosing cap and harness.
Pack sizes
Cardboard box with 1 container of 200 ml with auxiliary carton box containing dosing cap and harness.
1 container of 1l with auxiliary carton box containing dosing cap and harness.
1 container of 2.5l with auxiliary carton box containing dosing cap and harness.
1 container of 5l with auxiliary carton box containing dosing cap and harness.

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

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

{DD month YYYY}

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

{DD month 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).

ANNEX II

[Not applicable for MRP/DCP/SRP and national procedures]

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vecoxan 2.5 mg/ml oral suspension.

2. STATEMENT OF ACTIVE SUBSTANCES

Diclazuril 2.5 mg/ml

3. PACKAGE SIZE

200 ml
1 litre
2.5 litres
5 litres

4. TARGET SPECIES

Sheep (lambs) and cattle (calves).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Lambs and calves:
Meat and offal: zero days

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 3 months.

9. SPECIAL STORAGE PRECAUTIONS

Do not freeze.

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

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vecoxan 2.5 mg/ml oral suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Diclazuril 2.5 mg/ml

3. TARGET SPECIES

Sheep (lambs) and cattle (calves).

4. ROUTES OF ADMINISTRATION

Oral use.

Single administration of 1 mg diclazuril per kg body weight (i.e. 1 ml of the oral suspension per 2.5 kg body weight).
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:Lambs and calves:
Meat and offal: zero days

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 3 months.

7. SPECIAL STORAGE PRECAUTIONS

Do not freeze.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Vecoxan 2.5 mg/ml oral suspension

2. Composition

A white, oral suspension.
Each ml contains:
Active substance:
Diclazuril 2.5 mgExcipients:
Methyl para hydroxybenzoate (E218) 1.8 mg, Propyl para hydroxybenzoate 0.2 mg.

3. Target species

Sheep (lambs) and cattle (calves).

4. Indications for use

In lambs:
Prevention of coccidiosis caused by *Eimeria crandallis* and *Eimeria ovinoidalis*

In calves:
Prevention of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii*

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

5. Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special warnings:
If there is no recent and confirmed history of clinical coccidiosis, the presence of coccidia in the flock or herd should be confirmed by faecal sampling prior to treatment.
Cattle (calves): in certain cases, only a transient reduction of oocyst shedding may be achieved.
Suspected clinical cases of resistance to anticoccidials should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anticoccidial, an anticoccidial belonging to another pharmacological class and having a different mode of action should be used.

Special precautions for safe use in the target species:
The preferred timing of treatment is directed by the known epidemiology of *Eimeria* spp. and the presence of coccidia in the flock or herd should be confirmed by faecal sampling prior to treatment, if there is no recent and confirmed history of clinical coccidiosis.
Coccidiosis is an indicator of insufficient hygiene in the flock/pen. It is recommended to improve hygiene and to treat all lambs in the flock and all calves in a pen.
Frequent and repeated use of antiprotozoals may lead to the development of resistance in the target parasite.

To alter the course of an established clinical coccidial infection, in individual animals already showing signs of diarrhoea, additional supportive therapy may be required as diclazuril has no antimicrobial activity.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash hands after administration of the product.
Overdose:
In lambs: no signs of overdose were noted after administration of 5 times the recommended dose.
In 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.

7. Adverse events

Cattle (calves) and sheep (lambs):

Very rare (<1 animal / 10,000 animals treated, including isolated reports): Gastrointestinal signs (e.g. Diarrhoea[1,2]); Lethargy, Recumbency; Agitation; Neurologic signs (e.g. Paresis(muscle weakness))

[1] with possible presence of blood.
[2] in some treated animals, 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 the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system:

8. Dosage for each species, routes and method of administration

For oral use only.
Single administration of 1 mg diclazuril per kg body weight (i.e. 1 ml of the oral suspension per 2.5 kg body weight).

9. Advice on correct administration

Shake well before use**.**
To ensure a correct dosage, body weight should be determined as accurately as possible.
If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under - or overdosing. The use of suitably calibrated measuring equipment is recommended.

10. Withdrawal periods

Lambs and calves:

Meat and offal: zero days

11. Special storage precautions

Keep out of the sight and reach of children.

Do not freeze.
Do not use this veterinary medicinal product after the expiry date which is stated on the <label> <carton> after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the container: 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 1 container of 200 ml with auxiliary carton box containing dosing cap and harness.
1 container of 1l with auxiliary carton box containing dosing cap and harness.
1 container of 2.5l with auxiliary carton box containing dosing cap and harness.
1 container of 5l with auxiliary carton box containing dosing cap and harness.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD month YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder:

Manufacturer responsible for batch release:

Intervet Productions S.A.
Rue de Lyons
Igoville 27460
France

Local representatives and contact details to report suspected adverse reactions:

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