

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX – 200 ml presentation

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cocci-Drench 2.5 mg/ml Oral Suspension
Diclazuril

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: 2.5 mg diclazuril
Excipients: 1.8 mg methyl parahydroxybenzoate (E218) and 0.2 mg propyl parahydroxybenzoate

3. PHARMACEUTICAL FORM

Oral Suspension

4. PACKAGE SIZE

200 ml

5. TARGET SPECIES

Sheep (lambs) and cattle (calves).

6. INDICATION(S)

Anticoccidial oral drench.
For the treatment and prevention of coccidial infections in lambs caused, in particular by the more pathogenic *Eimeria* species, *E. crandallis* and *E. ovinoidalis*.
To aid in the control of coccidiosis in calves caused by *Eimeria bovis* and *Eimeria zuernii*.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.

Read the package leaflet before use.

Lambs

Therapeutic use: 1 mg diclazuril per kg bodyweight, in a single administration.

Prevention use: 1 mg diclazuril per kg bodyweight or 1 ml Cocci-Drench per 2.5 kg bodyweight at about 4-6 weeks of age at the time that coccidiosis can normally be expected on the farm. Under conditions of high infection pressure, a second treatment may be indicated about 3 weeks after the first dosing.

Calves

To aid in the control of coccidiosis:

1 mg diclazuril per kg bodyweight or 1 ml Cocci-Drench per 2.5 kg bodyweight administered as a single dose, 14 days after moving into a potentially high risk environment.

It is advocated to treat all lambs of the flock and all calves in a pen.
Shake well before use.

After using draw-off cap, re-close with original cap.

Cocci-Drench should be used by careful administration with a drenching gun. To ensure the correct dosage, bodyweight should be determined as accurately as possible.

Appropriately graduated drenching equipment must be used to allow accurate dosing. This is particularly important when administering small volumes.

8. WITHDRAWAL PERIOD(S)

Meat and offal: Lambs and calves: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

User warnings:

Wash hands after use.

10. EXPIRY DATE

EXP: {month/year}

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton.
Do not store above 30 °C.
Protect from frost.

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.

POM-VPS

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

Marketing Authorisation Holder and Distributor:

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

On behalf of:

United Farmers, The Coach House, 22 St John's Road, Corstorphine, Edinburgh,
EH12 6NZ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 06376/5036

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE – Label (Front and Back label)

200 ml presentation

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cocci-Drench 2.5 mg/ml Oral Suspension
Diclazuril

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: 2.5 mg diclazuril
Excipients: 1.8 mg methyl parahydroxybenzoate (E218) and 0.2 mg propyl parahydroxybenzoate

3. PHARMACEUTICAL FORM

Oral Suspension

4. PACKAGE SIZE

200 ml

5. TARGET SPECIES

Sheep (lambs) and cattle (calves).

6. INDICATION(S)

Anticoccidial oral drench.

For the treatment and prevention of coccidial infections in lambs. To aid in the control of coccidiosis in calves.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.

Read the package leaflet before use.

Lambs

Therapeutic use: 1 mg diclazuril per kg bodyweight, in a single administration or 1 ml Cocci-Drench per 2.5 kg bodyweight, in a single administration.

Prevention use: 1 mg diclazuril per kg bodyweight or 1 ml Cocci-Drench per 2.5 kg bodyweight at about 4-6 weeks of age at the time that coccidiosis can normally be expected on the farm. Under conditions of high infection pressure, a second treatment may be indicated about 3 weeks after the first dosing.

Calves

To aid in the control of coccidiosis caused by *E. bovis* and *E. zuernii*:

1 mg diclazuril per kg bodyweight or 1 ml Cocci-Drench per 2.5 kg bodyweight administered as a single dose, 14 days after moving into a potentially high risk environment.

It is advocated to treat all lambs of the flock and all calves in a pen.

Shake well before use.

After using draw-off cap, re-close with original cap.

Cocci-Drench should be used by careful administration with a drenching gun. To ensure the correct dosage, bodyweight should be determined as accurately as possible.

8. WITHDRAWAL PERIOD(S)

Meat and offal: Lambs and calves: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: {month/year}

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton.
Do not store above 30 °C. Protect from frost.

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

Read the package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

POM-VPS

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

Marketing Authorisation Holder and Distributor:

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

On behalf of:

United Farmers

16. MARKETING AUTHORISATION NUMBER(S)

Vm 06376/5036

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

PACKAGE LEAFLET:

Cocci-Drench 2.5 mg/ml Oral Suspension

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

Manufacturer responsible for batch release:

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cocci-Drench 2.5 mg/ml Oral Suspension

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

Each ml contains: 2.5 mg diclazuril

Excipients: 1.8 mg methyl parahydroxybenzoate (E218) and 0.2 mg propyl parahydroxybenzoate

White, homogeneous oral suspension.

4. INDICATION(S)

For the treatment and prevention of coccidial infections in lambs caused, in particular by the more pathogenic *Eimeria* species, *E. crandallis* and *E. ovinoidalis*.

To aid in the control of coccidiosis in calves caused by *Eimeria bovis* and *Eimeria zuernii*.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

None reported.

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

Sheep (lambs) and cattle (calves).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral use.

Lambs:

Therapeutic use: 1 mg diclazuril per kg bodyweight or 1 ml Cocci-Drench oral suspension per 2.5 kg bodyweight, as a single administration.

Preventative use: 1 mg diclazuril per kg bodyweight or 1 ml Cocci-Drench oral suspension per 2.5 kg bodyweight at about 4-6 weeks of age at the time that coccidiosis can normally be expected on the farm.

Under conditions of high infection pressure, a second treatment may be indicated about 3 weeks after the first dosing.

Calves:

To aid in the control of coccidiosis: 1 mg diclazuril per kg bodyweight or 1 ml Cocci-Drench oral suspension per 2.5 kg bodyweight, administered as a single dose, 14 days after moving into a potentially high risk environment.

If a satisfactory response is not observed, then further advice should be sought from your veterinary surgeon and the cause of the condition should be reviewed. It is good practice to ensure the cleanliness of calf housing.

For oral use in lambs and calves:

Bodyweight	Volume
5.0 kg	2 ml
7.5 kg	3 ml
10.0 kg	4 ml
12.5 kg	5 ml
15.0 kg	6 ml
20.0 kg	8 ml
25.0 kg	10 ml
50.0 kg	20 ml
75.0 kg	30 ml
100.0 kg	40 ml
150.0 kg	60 ml
175.0 kg	70 ml
200.0 kg	80 ml

It is advocated to treat all lambs of the flock and all calves in a pen. This will contribute to reduce the infection pressure and assure a better epidemiological control of the coccidiosis infection.

Treatment with diclazuril causes interruption of the coccidial cycle and of excretion of oocysts for approximately 2 to 3 weeks after administration.

9. ADVICE ON CORRECT ADMINISTRATION

Shake well before use.

After using draw-off cap, re-close with original cap.

Cocci-Drench should be used by careful administration with a drenching gun. To ensure the correct dosage, bodyweight should be determined as accurately as possible.

Appropriately graduated drenching equipment must be used to allow accurate dosing. This is particularly important when administering small volumes.

10. WITHDRAWAL PERIOD(S)

Meat and offal: Lambs and calves: Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 30 °C. Protect from frost.

12. SPECIAL WARNING(S)

Special precautions for use in animals:

Lambs:

On rare occasions, in highly susceptible lambs e.g. where they have been housed for long periods of time before being turned out onto heavily contaminated pasture, a severe scour has been seen shortly after dosing. In such cases, fluid therapy is essential and the use of a sulphonamide should be considered. It is also important to consider other potential pathogens that may be playing a role e.g. *Cryptosporidium*, *Nematodirus*, Rotavirus, *Giardia* and *E. coli*.

In the event of any stress factors (e.g. cold weather, other diseases) or high challenge (e.g. warm wet weather, inability to move lambs from infected pastures after dosing) the timing of the doses may need to be adjusted.

Calves:

Clinical coccidiosis generally occurs late in the parasite's life cycle after most of the damage to the calf's intestine has already been done. This severely damaged intestine can easily be infected by secondary bacteria and/or other agents. In cases of acute clinical coccidiosis treated with Cocci-Drench fluid therapy is essential and the use of an antibiotic should be considered. Symptoms of clinical disease may remain obvious in some calves treated with Cocci-Drench, even though oocyst excretion is reduced to a very low level, and overall prevalence of diarrhoea is decreased.

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

Wash hands after use.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose (symptoms, emergency procedures, antidotes):

Cocci-Drench oral suspension was given to lambs as a single dose up to 60 times the therapeutic dose. No adverse clinical effects were reported.

No adverse effects were noted either at 5 times the therapeutic dose administered four consecutive times with a 7-day interval.

In calves, the product was tolerated when administered up to five times the recommended dose rate.

Incompatibilities:

None known.

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

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

14. 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.

15. OTHER INFORMATION

For animal treatment only.

Pack sizes:

Cardboard box containing a 200 ml bottle with a high-density polypropylene draw-off cap.

1, 2.5 or 5 Litre bottle with a high-density polypropylene draw-off cap.

Not all pack sizes may be marketed.

Legal category: POM-VPS To be supplied only on veterinary prescription.

Vm 06376/5036

Marketing Authorisation Holder and Distributor:

Intervet International B.V.

Wim de Körverstraat 35

5831 AN Boxmeer

Netherlands

On behalf of:

United Farmers, The Coach House, 22 St John's Road, Corstorphine, Edinburgh, EH12 6NZ

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Front label – 1 Litre, 2.5 Litre and 5 Litre presentations

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cocci-Drench 2.5 mg/ml Oral Suspension
Diclazuril

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each ml contains: 2.5 mg diclazuril
Excipients: 1.8 mg methyl parahydroxybenzoate (E218) and 0.2 mg propyl parahydroxybenzoate

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 Litre
2.5 Litres
5 Litres

4. ROUTE(S) OF ADMINISTRATION

For oral use.

5. WITHDRAWAL PERIOD(S)

Meat and offal: Lambs and calves: Zero days.

6. BATCH NUMBER

Batch: {number}

7. EXPIRY DATE

EXP: {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Back label – 1 Litre, 2.5 Litre and 5 Litre presentations

{CONCERTINA LABEL¹. – Base Label and Top Label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cocci-Drench 2.5 mg/ml Oral Suspension
Diclazuril

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: 2.5 mg diclazuril
Excipients: 1.8 mg methyl parahydroxybenzoate (E218) and 0.2 mg propyl parahydroxybenzoate

3. PHARMACEUTICAL FORM

Oral Suspension

4. PACKAGE SIZE

1 Litre
2.5 Litres
5 Litres

5. TARGET SPECIES

Sheep (lambs) and cattle (calves).

6. INDICATION(S)

Read the package leaflet before use.

Anticoccidial oral drench.

For the treatment and prevention of coccidial infections in lambs.

To aid in the control of coccidiosis in calves.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Meat and offal: Lambs and calves: Zero days.

¹ For concertina labels, the immediate label template heading requirements must begin and end the proposal. The leaflet requirements should go in-between. The immediate label must be stuck to the container and be replicated on the outer facing part of the concertina label.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 30 °C. Protect from frost.

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

Read the package leaflet before use.

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.

POM-VPS

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

Marketing Authorisation Holder and Distributor:

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

On behalf of:

United Farmers, The Coach House, 22 St John's Road, Corstorphine, Edinburgh,
EH12 6NZ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 06376/5036

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

PACKAGE LEAFLET:

Cocci-Drench 2.5 mg/ml Oral Suspension

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

Manufacturer responsible for batch release:

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cocci-Drench 2.5 mg/ml Oral Suspension

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

Each ml contains: 2.5 mg diclazuril

Excipients: 1.8 mg methyl parahydroxybenzoate (E218) and 0.2 mg propyl parahydroxybenzoate

White, homogeneous oral suspension.

4. INDICATION(S)

For the treatment and prevention of coccidial infections in lambs caused, in particular by the more pathogenic *Eimeria* species, *E. crandallis* and *E. ovinoidalis*.

To aid in the control of coccidiosis in calves caused by *Eimeria bovis* and *Eimeria zuernii*.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

None reported.

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

Sheep (lambs) and cattle (calves).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral use.

Lambs:

Therapeutic use: 1 mg diclazuril per kg bodyweight or 1 ml Cocci-Drench oral suspension per 2.5 kg bodyweight, as a single administration.

Preventative use: 1 mg diclazuril per kg bodyweight or 1 ml Cocci-Drench oral suspension per 2.5 kg bodyweight at about 4-6 weeks of age at the time that coccidiosis can normally be expected on the farm.

Under conditions of high infection pressure, a second treatment may be indicated about 3 weeks after the first dosing.

Calves:

To aid in the control of coccidiosis: 1 mg diclazuril per kg bodyweight or 1 ml Cocci-Drench oral suspension per 2.5 kg bodyweight, administered as a single dose, 14 days after moving into a potentially high risk environment.

If a satisfactory response is not observed, then further advice should be sought from your veterinary surgeon and the cause of the condition should be reviewed. It is good practice to ensure the cleanliness of calf housing.

For oral use in lambs and calves:

Bodyweight	Volume
5.0 kg	2 ml
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20.0 kg	8 ml
25.0 kg	10 ml
50.0 kg	20 ml
75.0 kg	30 ml
100.0 kg	40 ml
150.0 kg	60 ml
175.0 kg	70 ml
200.0 kg	80 ml

It is advocated to treat all lambs of the flock and all calves in a pen. This will contribute to reduce the infection pressure and assure a better epidemiological control of the coccidiosis infection.

Treatment with diclazuril causes interruption of the coccidial cycle and of excretion of oocysts for approximately 2 to 3 weeks after administration.

9. ADVICE ON CORRECT ADMINISTRATION

Shake well before use.

After using draw-off cap, re-close with original cap.

Cocci-Drench should be used by careful administration with a drenching gun. To ensure the correct dosage, bodyweight should be determined as accurately as possible.

Appropriately graduated drenching equipment must be used to allow accurate dosing. This is particularly important when administering small volumes.

10. WITHDRAWAL PERIOD(S)

Meat and offal: Lambs and calves: Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 30 °C. Protect from frost.

12. SPECIAL WARNING(S)

Special precautions for use in animals:

Lambs:

On rare occasions, in highly susceptible lambs e.g. where they have been housed for long periods of time before being turned out onto heavily contaminated pasture, a severe scour has been seen shortly after dosing. In such cases, fluid therapy is essential and the use of a sulphonamide should be considered. It is also important to consider other potential pathogens that may be playing a role e.g. *Cryptosporidium*, *Nematodirus*, Rotavirus, *Giardia* and *E. coli*.

In the event of any stress factors (e.g. cold weather, other diseases) or high challenge (e.g. warm wet weather, inability to move lambs from infected pastures after dosing) the timing of the doses may need to be adjusted.

Calves:

Clinical coccidiosis generally occurs late in the parasite's life cycle after most of the damage to the calf's intestine has already been done. This severely damaged intestine can easily be infected by secondary bacteria and/or other agents. In cases of acute clinical coccidiosis treated with Cocci-Drench fluid therapy is essential and the use of an antibiotic should be considered. Symptoms of clinical disease may remain obvious in some calves treated with Cocci-Drench, even though oocyst excretion is reduced to a very low level, and overall prevalence of diarrhoea is decreased.

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

Wash hands after use.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose (symptoms, emergency procedures, antidotes):

Cocci-Drench oral suspension was given to lambs as a single dose up to 60 times the therapeutic dose. No adverse clinical effects were reported.

No adverse effects were noted either at 5 times the therapeutic dose administered four consecutive times with a 7-day interval.

In calves, the product was tolerated when administered up to five times the recommended dose rate.

Incompatibilities:

None known.

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

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

14. 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.

15. OTHER INFORMATION

For animal treatment only.

Pack sizes:

Cardboard box containing a 200 ml bottle with a high-density polypropylene draw-off cap.

1, 2.5 or 5 Litre bottle with a high-density polypropylene draw-off cap.

Not all pack sizes may be marketed.

Legal category: POM-VPS To be supplied only on veterinary prescription.

Vm 06376/5036

Marketing Authorisation Holder and Distributor:

Intervet International B.V.

Wim de Körverstraat 35

5831 AN Boxmeer

Netherlands

On behalf of:

United Farmers, The Coach House, 22 St John's Road, Corstorphine, Edinburgh,
EH12 6NZ

Approved 25 March 2025

Gavin Hall