ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

CONTAINER
Case 1: As there is no outer packaging, all the information of the package leaflet is conveyed on the container. Consequently, no separate leaflet is provided in compliance with the current QRD Template

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Distocur 34 mg/ml oral suspension for cattle and sheep

2. COMPOSITION

Active substance:

Oxyclozanide	34.0 mg/ml
Excipients:	
Methyl parahydroxybenzoate (E218)	1.35 mg/ml
Propyl parahydroxybenzoate	0.15 mg/ml

Whitish to beige oral suspension

3. PACKAGE SIZE

1L
5L
10L

4. TARGET SPECIES

Cattle and sheep

5. INDICATIONS FOR USE

Indications for use

For treatment of infections caused by the adult stage of *Fasciola hepatica*, sensitive to oxyclozanide.
For elimination of gravid tapeworm segments (*Moniezia* spp.).

6. CONTRAINDICATIONS

Contraindications

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

7. SPECIAL WARNINGS

Special warnings

Special warnings:
To date no resistance to oxyclozanide has been reported. Use of the product should be based on local (regional, farm) epidemiological information about susceptibility of *Fasciola hepatica* and recommendations on how to limit further selection for resistance to anthelmintics.
Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- Underdosing, which may be due to underestimation of body weight, misadministration of the product or lack of calibration of the dosing device (if any).

Suspected clinical cases of resistance to anthelmintics 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 anthelmintic, an anthelmintic belonging to another pharmaceutical class and having a different mode of action should be used.

At normal dose levels, oxyclozanide is not active against immature flukes present in liver tissue.
Milking cattle, particularly high yielders, may show a reduction in yield, occasionally of 5 % or more, for about 48 hours after handling. The effect of this small loss may be minimised by spreading herd dosing over a period of about one week.

Special precautions for safe use in the target species:
To avoid injuries of the pharyngeal region, care should be taken when administering the veterinary medicinal product by dosing gun.
Adverse events (see section Adverse events) are occasionally enhanced in animals suffering from severe impairment of liver function and/or dehydration at the time of dosing.
The physical condition of animals undergoing treatment should always be observed, particularly of those in advanced pregnancy and/or under stress from adverse weather conditions, poor nutrition, penning, handling, etc.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The veterinary medicinal product may cause irritation to skin, eyes and mucous membranes.
People with known hypersensitivity to oxyclozanide or any of the excipients should avoid contact with the veterinary medicinal product.
Wash hands after use.
Operators should wear impermeable rubber gloves when applying the veterinary medicinal product.
Do not smoke, eat or drink while handling the veterinary medicinal product.
In case of contact with the veterinary medicinal product, rinse the affected area immediately with plenty of water.
Contaminated clothing should be removed immediately.

In the event of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:
Oxyclozanide is toxic to dung fauna. The risk can be reduced by avoiding too frequent and repeated use of oxyclozanide in cattle.

Pregnancy and lactation:
Can be used during pregnancy and lactation.
However, care should be taken when treating heavily pregnant animals and animals under stress from adverse weather conditions, poor nutrition, penning, handling, etc.
Laboratory studies with oxyclozanide during different phases of reproduction have not produced any evidence of teratogenic or foetotoxic effects.

Fertility:
Laboratory studies with oxyclozanide during different phases of reproduction have not produced any evidence of negative effects on fertility.

Interactions with other medicinal products and other forms of interaction:
No information is available on the safety and efficacy of this veterinary medicinal product when used with any other veterinary medicinal product.
A decision to use this veterinary medicinal product before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

Overdose:
The adverse events (see section Adverse events) observed at normal doses are more pronounced at increased doses. At doses of 50 mg/kg there is a risk of death. The effects of oxyclozanide overdosage are dullness and some loosening of faeces in sheep and possible diarrhoea, inappetance and loss of weight in cattle. These effects are very rarely enhanced in animals suffering from severe impairment of liver function and/or dehydration at the time of dosing.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

8. ADVERSE EVENTS

Adverse events

Cattle and sheep:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Loose stool, frequent defecation, inappetence[1]

[1] Transient

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, 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 on this label, or via your national reporting system.

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

Oral use. Give as an oral drench.

Dosage:
Cattle:
10 mg oxyclozanide per kg body weight, corresponding to 3 ml of veterinary medicinal product per 10 kg body weight. For animals above 350 kg: 3.5g oxyclozanide per animal, i.e. 103 ml of veterinary medicinal product.

Sheep:
15 mg oxyclozanide per kg body weight, corresponding to 4.4 ml of veterinary medicinal product per 10 kg body weight. For animals above 45 kg: 0.68g oxyclozanide per animal, i.e. 20 ml of veterinary medicinal product.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

Shake the suspension at least 5 times before use.
To ensure a correct dosage, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked. 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.

11. WITHDRAWAL PERIODS

Withdrawal periods

Cattle:
Meat and offal: 13 days.
Milk: 4.5 days (108 hours).

Sheep:
Meat and offal: 14 days.
Milk: 7 days (168 hours).

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.
This veterinary medicinal product as packed for sale does not require any special storage conditions.
After first opening, do not store above 25°C.

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

13. SPECIAL PRECAUTIONS FOR DISPOSAL

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 how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 28365/3002

Pack sizes

PE container of 1L, 5L and 10L.

Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

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

17. CONTACT DETAILS

Contact details

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

Dopharma Research B.V.

Zalmweg 24

4941 VX Raamsdonksveer

The Netherlands

Manufacturer responsible for batch release:
Dopharma France S.A.S.
23 Rue du Prieuré – Saint Herblon
FR-44150 Vair sur Loire

Local representative and contact details to report suspected adverse reactions:

18. OTHER INFORMATION

Other information

Environmental properties:
Faeces containing oxyclozanide excreted onto pasture by treated animals may reduce the abundance of dung feeding organisms which may impact on dung degradation.
Oxyclozanide is persistent in soils.

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use by…
Shelf life after first opening the immediate packaging: 1 year.

21. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Container
Case 2: When all the information of the package leaflet cannot be conveyed on the container. Consequently, a separate leaflet is provided in compliance with the current QRD Template.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Distocur 34 mg/ml oral suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Oxyclozanide 34.0 mg/ml

3. PACKAGE SIZE

1L
5L
10L

4. TARGET SPECIES

Cattle and sheep

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Withdrawal period:

Cattle:
Meat and offal: 13 days.
Milk: 4.5 days (108 hours).

Sheep:
Meat and offal: 14 days.
Milk: 7 days (168 hours).

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 1 year
Once opened, use by…

9. SPECIAL STORAGE PRECAUTIONS

After first opening, do not store above 25°C.

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

Dopharma Research B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 28365/3002

15. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Case 2: If all the information of the package leaflet cannot be conveyed on the container.

1. Name of the veterinary medicinal product

Distocur 34 mg/ml oral suspension for cattle and sheep

2. Composition

Each ml contains:

Active substance:
Oxyclozanide 34.0 mg

Excipients:
Methyl parahydroxybenzoate (E218) 1.35 mg
Propyl parahydroxybenzoate 0.15 mg

Whitish to beige oral suspension.

3. Target species

Cattle and sheep.

4. Indications for use

For treatment of infections caused by the adult stage of *Fasciola hepatica,* sensitive to oxyclozanide.
For elimination of gravid tapeworm segments (*Moniezia* spp.).

5. Contraindications

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

6. Special warnings

Special warnings:
To date no resistance to oxyclozanide has been reported. Use of the product should be based on local (regional, farm) epidemiological information about susceptibility of *Fasciola hepatica* and recommendations on how to limit further selection for resistance to anthelmintics.
Care should be taken to avoid the following practices as they increase the risk of development of resistance and could ultimately result in ineffective therapy:
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Fertility:
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Shelf life after first opening the immediate packaging: 1 year.

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Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 28365/3002

PE container of 1L, 5L and 10L.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

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16. Contact details

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Zalmweg 24
4941 VX Raamsdonksveer
The Netherlands
Tel +31-162-582000
pharmacovigilance@dopharma.com

Manufacturer responsible for batch release:
Dopharma France S.A.S.
23 Rue du Prieuré – Saint Herblon
FR-44150 Vair sur Loire

Local representative and contact details to report suspected adverse reactions:

17. Other information

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Approved 23 November 2023