SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Distocur 34 mg/ml Oral Suspension for Cattle and Sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Oxyclozanide	34.0 mg

Excipients:

Methyl parahydroxybenzoate (E218)	1.35 mg
Propyl parahydroxybenzoate	0.15 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension.

Whitish to beige oral suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle and Sheep.

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

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

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals

To avoid injuries of the pharyngeal region, care should be taken when administering the veterinary medicinal product by dosing gun.
Adverse events (see section 4.6) 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 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.

Other precautions

Not applicable.

4.6 Adverse events (frequency and seriousness)

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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet or label for respective contact details.

4.7 Use during pregnancy, lactation or lay

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.

4.8 Interaction 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.

4.9 Amount(s) to be administered and administration route

Oral use. Give as an oral drench. Shake the suspension at least 5 times before use.

To ensure administration of a correct dose, 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.

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: 3.5 g 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: 0.68 g oxyclozanide per animal, i.e. 20 ml of veterinary medicinal product.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

The adverse events (see section 4.6) 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 with severe liver damage and/or dehydration at the time of dosing.

4.11 Withdrawal period(s)

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

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

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, Phenol derivatives, incl. salicylanilides, oxyclozanide

ATCvet Code: QP52AG06

5.1 Pharmacodynamic properties

Oxyclozanide is an anthelmintic of the salicylanilide group. The salicylanilides are proton ionophores, which act as specific uncouplers of mitochondrial oxidative phosphorylation, disrupting the metabolism of the parasite.

The chemical structure of salicylanilides is characterised by the presence of an unstable proton. They are lipophilic molecules which allow the passage of protons across membranes, especially through the inner mitochondrial membrane.

Oxyclozanide has flukicidal activity against the adult stage of *Fasciola hepatica*. Its efficacy against cestodes is limited to the removal of segments of the tapeworm *Moniezia.*spp.

5.2 Pharmacokinetic particulars

Oxyclozanide is slowly absorbed after oral administration.
In cattle, the peak plasma concentration (nearly 13 µg/ml) is observed 13 hours after administration. The mean elimination half-life is 11 hours.
In sheep, the peak plasma concentration (nearly 31 µg/ml) is observed 18 hours after administration. The mean elimination half-life is 11 hours.
Excretion is predominantly faecal with biliary excretion being the most important route of elimination.

5.3 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate
Aluminium magnesium silicate
Carmellose sodium (E466)
Sodium laurilsulfate
Monohydrate citric acid (E330)
Sodium citrate (E331)
Purified water

6.2 Major Incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the container: 1 year.

6.4 Special precautions for storage

This veterinary medicinal product as packaged for sale does not require any special storage conditions.
After first opening, do not store above 25°C.

6.5 Nature and composition of immediate packaging

Opaque high density polyethylene container (1L, 5L and 10L) closed by opaque high density polyethylene screw cap.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7 MARKETING AUTHORISATION HOLDER

Dopharma Research B.V.
Zalmweg 24
4941 VX Raamsdonksveer
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 28365/5005

9. DATE OF FIRST AUTHORISATION

16 November 2016

10. DATE OF REVISION OF THE TEXT

November 2023

PROHIBITION OF SALE, SUPPLY AND/OR USE

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Approved 23 November 2023