# 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 suspension.

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Cattle and sheep.

### 4.2 Indications for use, specifying the target species

Cattle and sheep:
Treatment of infections caused by the adult stage of *Fasciola hepatica,* sensitive to oxyclozanide.
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 trematodes 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 damage to the pharyngeal region, care should be taken when administering by dosing gun.
Adverse effects (see section 4.6) are occasionally enhanced in animals suffering from severe liver damage and/or dehydration at the time of dosing.
Due regard must always be given to the physical condition of animals undergoing treatment, particularly 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
This 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 rubber gloves when applying the product.
Do not smoke, eat or drink while handling the product.
In case of contact with the 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.

Other precautions
Oxyclozanide is toxic to dung fauna and aquatic organisms. The risk can be reduced by avoiding too frequent and repeated use of oxyclozanide in cattle. Treated cattle must not graze near watercourses and must not have access to water bodies for 5 days after treatment.

**4.6 Adverse reactions (frequency and seriousness)**

Slight softening of the faeces with animal showing increased frequency of defecation and transient inappetence may appear very rarely.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated )
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

**4.7 Use during pregnancy, lactation or lay**

Laboratory studies during different phases of reproduction have not produced any evidence of teratogenic or foetotoxic effects, or negative effects on fertility.
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.

**4.8 Interaction with other medicinal products and other forms of interactions**

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 Amounts 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:
Dose according to body weight at a rate of 10 mg oxyclozanide per kg body weight, corresponding to 3 ml of product per 10 kg body weight. For animal above 350 kg, dose is 3.5 g oxyclozanide per animal, i.e. 103 ml of product.

Sheep:
Dose according to body weight at a rate of 15 mg oxyclozanide per kg body weight, corresponding to 4.4 ml of product per 10 kg body weight. For animal above 45 kg, dose is 0.68 g oxyclozanide per animal, i.e. 20 ml of product.

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

The adverse reactions (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 or IMMUNOLOGICAL 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*.

**5.2 Pharmacokinetic particulars**

Oxyclozanide is slowly absorbed after oral administration.
In cattle, the peak plasma concentration (nearly 13 micrograms/ml) is observed 13 hours after administration. The mean elimination half-life is 11 hours.
In sheep, the peak plasma concentration (nearly 31 micrograms/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.

**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 toxic to aquatic organisms. 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: use within 1 year.

### 6.4 Special precautions for storage

Do not store above 25°C after first opening.

### 6.5 Nature and composition of immediate packaging

One white high density polyethylene container (1L, 5L and 10L) closed by one white high density polyethylene cap.
Not all pack sizes may be marketed.

### 6.6 Special precautions for the disposal of unused veterinary medicinal products 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
Netherlands

## 8 MARKETING AUTHORISATION NUMBER(S)

VPA10791/013/001

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13 January 2017

## 10 DATE OF REVISION OF THE TEXT

August 2019