

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

INTRA DYSOVINOL 499 mg/ml solution for use in drinking water for pigs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml of solution contains:

Active substance:

Zinc disodium EDTA 499 mg

Excipient:

Sodium methyl parahydroxybenzoate (E219) 1.3 mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for use in drinking water.

Clear, green liquid.

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs (fattening pigs).

4.2 Indications for use, specifying the target species

For the treatment and metaphylaxis of dysentery due to *Brachyspira hyodysenteriae* infection in fattening pigs (25-125 kg).

4.3 Contraindications

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

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

None known.

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

This product may cause eye irritation. Avoid eye contact, including hand-to eye contact. Wear safety glasses. Wash hands after use. In case of contact with eyes, rinse with plenty of water, and seek medical attention if irritation persists.

People with known hypersensitivity to the active substances or any of the excipients should avoid contact with the veterinary medicinal product.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interactions

No data available.

4.9 Amounts to be administered and administration route

For oral use in drinking water.

Dose 11.3 mg zinc disodium EDTA per kg of bodyweight per day, corresponding with 0.023 ml veterinary medicinal product per kg of bodyweight per day, during 6 consecutive days.

The intake of drinking water depends on the clinical condition of the animals. For a correct dosage, calculate the amount of veterinary medicinal product to dose by the following formula:

$$\frac{0.023 \times \text{Average bodyweight (kg) per animal}}{\text{Average daily water consumption (litre) per animal}} = \dots \text{ ml product per litre drinking water}$$

To calculate a correct dosage, the bodyweight and average daily water consumption should be determined as accurately as possible.

Medicated drinking water should be replaced every 24 hours. The medicated drinking water should be the sole source of drinking water for the treatment duration.

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

No information available.

4.11 Withdrawal period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antidiarrheals, intestinal anti-inflammatory / anti-infective agents.

ATC vet code: QA07XA92

5.1 Pharmacodynamic properties

The pharmacodynamic effect of zinc disodium EDTA on intestinal *Brachyspira hyodysenteriae* infection in pigs is not fully established. *In vivo* studies have shown that after treatment with zinc disodium EDTA *Brachyspira hyodysenteriae* could not be detected anymore in the intestinal tract. *In vivo* studies have also demonstrated that zinc disodium EDTA can have a positive effect on the recovery of intestinal cells.

5.2 Pharmacokinetic particulars

The product is administered orally, through drinking water. Zinc disodium EDTA is poorly absorbed and predominantly excreted through faeces.

5.3 Environmental properties

Zinc disodium EDTA classifies as very persistent (vP) in soil. However, no environmental risks are involved.

Zinc disodium EDTA may leach to groundwater resulting in a groundwater concentration exceeding the groundwater quality standard for pesticides and biocides as set in the EU Groundwater Directive 2014/80/EU and EU Drinking Water Directive (98/83/EC). However, no risks for humans and the environment are expected.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water
Sodium methyl parahydroxybenzoate (E219)
Brilliant blue FCF (E133)
Tartrazine (E102)

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: 36 months.
Shelf life after first opening the immediate packaging: 2 months.
Shelf life of the medicated drinking water: 24 hours.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special temperature storage conditions.
Do not refrigerate or freeze.

6.5 Nature and composition of immediate packaging

5, 10 and 20 liter high density polyethylene container with high density polyethylene screw cap and seal ring.
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 it should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Intracare B.V.
Voltaweg 4
5466 AZ
Veghel
Netherlands

8 MARKETING AUTHORISATION NUMBER(S)

VPA10409/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 06 September 2019

10 DATE OF REVISION OF THE TEXT