

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

Each ml of solution contains:

Active substance:

Zinc disodium EDTA

499 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Sodium methyl parahydroxybenzoate (E219)	1.3 mg
Brilliant blue FCF (E133)	0.005 mg
Tartrazine (E102)	0.005 mg
Water, purified	

Clear, green solution.

3. CLINICAL PARTICULARS

3.1 Target species

Pigs (fattening).

3.2 Indications for use, specifying the target species

For the treatment and metaphylaxis of dysentery due to *Brachyspira hyodysenteriae* infection in fattening pigs.

The presence of the disease in the group must be established before the product is used.

3.3 Contraindications

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

3.4 Special warnings

Animals with reduced water intake and/or in a debilitated condition should be treated parenterally.

Animals should be penned in homogeneous groups of similar bodyweights to facilitate accurate dosing during group treatment via the drinking water.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use of the veterinary medicinal product should be based on the identification of the target pathogen. If this is not possible, empirical therapy should be based on the presence of clinical signs diagnostic for the presence of the target pathogen and experience at the farm level, as well as available epidemiological information. In addition, veterinary medicines policies should also be taken into consideration when using this product including those set at a local/regional level.

Although literature is available describing an association between high zinc levels in feed and a risk of co-selection for antimicrobial resistance, resistance development from the use of this product is unlikely at the relatively lower therapeutic dose.

However, this product is not a substitute for good pig husbandry and hygiene practices and is not for prophylactic use. The product should not be used as part of a herd health program.

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. In case of contact with eyes, rinse with plenty of water, and seek medical attention if irritation persists, showing the package leaflet or the label to the physician. Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None known.

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 for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy or lactation.

3.8 Interaction with other medicinal products and other forms of interaction

No data available.

3.9 Administration routes and dosage

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 bodyweight per day, during 6 consecutive days.

The intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of zinc disodium EDTA in drinking water may need to be adjusted accordingly. Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{0.023 \times \text{Average bodyweight (kg) of animals to be treated}}{\text{Average daily water intake (litre) per animal}} = \text{.... ml veterinary medicinal product per litre drinking water}$$

To calculate a correct dosage, the bodyweight and average daily water consumption should be determined as accurately as possible. For example, the use of suitably calibrated weighing equipment is recommended.

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. The treated pigs should be placed under special observation. On each of the six days of treatment, unmedicated drinking water should not be given unless the full daily amount of medicated drinking water has been ingested by pigs.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

A dose of the veterinary medicinal product of 0.035 ml per kg bodyweight (1.5x recommended dose) for 6 days, did not result in adverse effects.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal period(s)

Meat and offal: Zero days.

4. PHARMACOLOGICAL PROPERTIES

4.1 ATC Vet Code: QA07XA91

4.2 Pharmacodynamic properties

The pharmacodynamic effect of zinc disodium EDTA on intestinal *Brachyspira hyodysenteriae* infection in pigs is not fully established. An *in vitro* study performed with *E. coli* model suggests that zinc disodium EDTA may act by prevention of adhesion of the pathogen to intestinal cells. *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.

4.3 Pharmacokinetic particulars

The product is administered orally, through drinking water. An *in vivo* study was performed to investigate the pharmacodynamic properties of the active substance, zinc disodium EDTA. This demonstrated that the administered zinc is not significantly absorbed; up to 90% of the zinc is not absorbed and excreted through faeces. The systemic availability (in terms of plasma levels of zinc) was not significantly increased when the product was administered at high doses. Even at the highest dose administered during this study (app. 6.5 times the proposed dose) no significant increase in bioavailability was seen and the majority of the dose was excreted. Any part of the dose absorbed systemically following oral administration of the veterinary medicinal product is not expected to result in accumulation of zinc during therapeutic use of this product and the absorbed fraction will be rapidly excreted via the kidneys in the urine.

Environmental properties

Zinc disodium EDTA is very persistent in some soils and may leach to groundwater, resulting in concentrations exceeding the groundwater quality standard for veterinary medicines of 0.1 µg/l. However, no risks for humans and the environment are expected.

5. PHARMACEUTICAL PARTICULARS

5.1 Major Incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf life after first opening the immediate packaging: 2 months.

Shelf life after dilution according to directions: 24 hours.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special temperature storage conditions.

Do not refrigerate or freeze.

5.4 Nature and composition of immediate packaging

High density polyethylene container of 5, 10 or 20 litre with high density polyethylene screw cap and seal ring.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater.

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intracare BV

7. MARKETING AUTHORISATION NUMBER

Vm 41870/5000

8. DATE OF FIRST AUTHORISATION

30 January 2026

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

January 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription (POM-V)

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall

Approved: 26 February 2026