ANNEX I

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
Purified water	

Clear, green liquid.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (for fattening).

3.2 Indications for use for each target species

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

3.3 Contraindications

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

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Although literature is available describing an association between high zinc levels in feed and a risk of co-selection for antimicrobial resistance, resistance development due to the use of this product is unlikely.

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. Personal protective equipment consisting of safety glasses should be worn when handling the veterinary medicinal product. 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 substance or any of the excipients should avoid contact with the veterinary medicinal product.

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 its local representative or the national competent authority via the national reporting system.
See also the combined label and package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Not applicable.

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 of 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 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:

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

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.

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

No information available.

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 periods

Zero days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QA07XA92.

4.2 Pharmacodynamics

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-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 Pharmacokinetics

The product is administered orally, through drinking water. An *in vivo* study performed demonstrated that the administered zinc is not significantly absorbed; up to 90% of the zinc is not absorbed and excreted through faeces. A significant increased systemic availability (in terms of plasma levels) of the product did not to occur, even at the high dose applied in this study (app. 6.5 times the proposed dose).

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.

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: 36 months.
Shelf life after first opening the immediate packaging: 2 months.
Shelf life of the medicated drinking water: 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 liter 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 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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intracare B.V.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:

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

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

NL, PT, HU, IE, SK, PL, RO, AT, BG, MT, LU, ES: Veterinary medicinal product subject to prescription.
EL, LT, EE, HR, CY, LV: Veterinary medicinal product not subject to prescription.

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