

[Version 9.1,11/2024]

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zantoral 30 mg/ml, Oral solution for dogs.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Ranitidine base 30.00 mg
(equivalent to ranitidine hydrochloride 33.479 mg)

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Methyl parahydroxybenzoate (E218)	1.80 mg
Propyl parahydroxybenzoate	0.20 mg
Hypromellose	
Ethanol (96 %)	
Sorbitol liquid non crystallising	
Sodium dihydrogen phosphate dihydrate	
Sodium phosphate dodecahydrate	
Sodium hydroxide (for pH adjustment)	
Phosphoric acid (for pH adjustment)	
Purified water	

Colourless or slightly yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

Control of gastric acid secretion and reduction of vomiting in the course of acute and chronic inflammation, including gastric ulcer, gastro-oesophageal reflux and reflux oesophagitis. In the treatment of drug-induced gastric and duodenal ulcers, particularly those caused by NSAIDs (non-steroidal anti-inflammatory drugs).

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in animals with renal or hepatic impairment.

3.4 Special warnings

It is advisable to foresee the appropriate dietary measures.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Administration of ranitidine, like all H₂ receptor inhibitors, may promote intragastric bacterial growth by decreasing gastric acidity.

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

Persons with known hypersensitivity to ranitidine should avoid contact with the veterinary medicinal product. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Avoid introduction of contamination.

In case of accidental skin or eye contact wash thoroughly with water.

Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs: 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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established in the target species during pregnancy and lactation. Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

Do not administer at the same time as other veterinary medicinal products that are weak acids, as ranitidine causes a change in gastric pH that may influence bioavailability.

3.9 Administration routes and dosage

Oral use.

The recommended treatment dose is 2 mg ranitidine base/kg body weight (equivalent to 0.2 ml of this veterinary medicinal product per 3 kg body weight) given orally twice daily for up to 20 consecutive days. The product may be administered directly into the oral cavity or mixed with a mouthful of food, using the graduated syringe included in the pack.

Treatment regimen according to the weight of the animal:

Weight of dog kg	Millilitres of product	Weight of dog kg	Millilitres of product
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1.5	0.1 ml / twice daily	24	1.6 ml / twice daily
3	0.2 ml / twice daily	25.5	1.7 ml / twice daily
4.5	0.3 ml / twice daily	27	1.8 ml / twice daily
6	0.4 ml / twice daily	28.5	1.9 ml / twice daily
7.5	0.5 ml / twice daily	30	2.0 ml / twice daily
9	0.6 ml / twice daily	33	2.2 ml / twice daily
10.5	0.7 ml / twice daily	36	2.4 ml / twice daily
12	0.8 ml / twice daily	39	2.6 ml / twice daily
13.5	0.9 ml / twice daily	42	2.8 ml / twice daily
15	1.0 ml / twice daily	45	3 ml / twice daily
16.5	1.1 ml / twice daily	48	3.2 ml / twice daily
18	1.2 ml / twice daily	51	3.4 ml / twice daily
19.5	1.3 ml / twice daily	54	3.6 ml / twice daily
21	1.4 ml / twice daily	57	3.8 ml / twice daily
22.5	1.5 ml / twice daily	60	4 ml / twice daily
To be administered for up to 20 consecutive days			

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

Ranitidine has a wide safety margin. 40 mg of ranitidine per kg body weight daily for 5 consecutive weeks was well tolerated in dogs.

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

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QA02BA02

4.2 Pharmacodynamics

Ranitidine is a competitive antagonist for histamine H₂ receptors; it has high selectivity and potency for these last, but principally for those present in the gastric wall, with limited or no activity on H₂ receptors of other organs and tissues.

Its effect is dose-dependent. It reduces baseline and nocturnal acid secretion and acid secretion induced by food: it also reduces the volume of gastric juice and its H⁺ concentration.

4.3 Pharmacokinetics

After oral administration ranitidine reaches peak blood concentration 0.5 -1.0 hour after treatment. Its elimination half-life ($t_{1/2}$) is approximately 3 h.

After oral administration it is distributed effectively within the body and its absorption is not influenced by state of gastric filling. Bioavailability is 74%. Ranitidine does not cross the blood-brain barrier.

Ranitidine is metabolised in the liver and is excreted principally in the urine. The drug is eliminated chiefly in unchanged form (40% of the dose).

Evaluation to identify metabolites in urine shows that in dogs it is transformed into the N-oxide compound (ranitidine N-oxide), while only traces of other metabolites, such as ranitidine S-oxide, desmethyl ranitidine and furoic acid, are evident.

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: 18 months.

Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Do not store above 25 °C.

Store in the original container.

Keep the container tightly closed.

5.4 Nature and composition of immediate packaging

HDPE bottles of 12 ml, 24 ml or 48 ml with HDPE stoppers and LDPE plugs.

3 ml polypropylene/silicone syringe, graduated every 0.1 ml to 3 ml.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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

Emdoka

7. MARKETING AUTHORISATION NUMBER(S)

XXXX

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

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

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD OUTER CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zantoral 30 mg/ml Oral solution for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Ranitidine base 30.00 mg (equivalent to ranitidine hydrochloride 33.479 mg)

3. PACKAGE SIZE

12 ml

24 ml

48 ml

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

Store in the original container.

Keep the container tightly closed.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Emdoka

14. MARKETING AUTHORISATION NUMBERS

XXXX

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle (HDPE) of 12 ml, 24 ml or 48 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zantoral

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each ml contains:

Ranitidine base 30.00 mg (equivalent to ranitidine hydrochloride 33.479 mg)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 28 days.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Zantoral 30 mg/ml, Oral solution for dogs

2. Composition

Each ml contains:

Active substance

Ranitidine base 30.00 mg
(equivalent to ranitidine hydrochloride 33.479 mg)

Excipients

Methyl parahydroxybenzoate (E 218) 1.80 mg
Propyl parahydroxybenzoate 0.20 mg

Colourless or slightly yellow solution.

3. Target species

Dogs.

4. Indications for use

Control of gastric acid secretion and reduction of vomiting in the course of acute and chronic inflammation, including gastric ulcer, gastro-oesophageal reflux and reflux oesophagitis. In the treatment of drug-induced gastric and duodenal ulcers, particularly those caused by NSAIDs (non-steroidal anti-inflammatory drugs).

5. Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in animals with renal or hepatic impairment.

6. Special warnings

Special warnings:

It is advisable to foresee the appropriate dietary measures.

Special precautions for safe use in the target species:

Administration of ranitidine, like all H₂ receptor inhibitors, may promote intragastric bacterial growth by decreasing gastric acidity.

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

Persons with known hypersensitivity to ranitidine should avoid contact with the veterinary medicinal product. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Avoid introduction of contamination.

In case of accidental skin or eye contact wash thoroughly with water.

Wash hands after use.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established in the target species during pregnancy and lactation. Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

Do not administer at the same time as other veterinary medicinal products that are weak acids, as ranitidine causes a change in gastric pH that may influence bioavailability.

Overdose:

Ranitidine has a wide safety margin. 40 mg of ranitidine per kg body weight daily for 5 consecutive weeks was well tolerated in dogs.

Major incompatibilities:

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

7. Adverse events

Dogs: None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

Oral use.

The recommended treatment dose is 2 mg ranitidine base/kg body weight (equivalent to 0.2 ml of this veterinary medicinal product per 3 kg body weight) given orally twice daily for up to 20 consecutive days. The product may be administered directly into the oral cavity or mixed with a mouthful of food, using the graduated syringe included in the pack.

Treatment regimen according to the weight of the animal:

Weight of dog kg	Millilitres of product	Weight of dog kg	Millilitres of product
1.5	0.1 ml / twice daily	24	1.6 ml / twice daily
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19.5	1.3 ml / twice daily	54	3.6 ml / twice daily
21	1.4 ml / twice daily	57	3.8 ml / twice daily
22.5	1.5 ml / twice daily	60	4 ml / twice daily
To be administered for up to 20 consecutive days			

9. Advice on correct administration

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25 °C.

Store in the original container.

Keep the container tightly closed.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 28 days.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

XXXX

HDPE bottles of 12 ml, 24 ml or 48 ml with HDPE stoppers and LDPE plugs.

3 ml polypropylene/silicone syringe, graduated every 0.1 ml to 3 ml.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

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

16. Contact details

Marketing authorisation holder:

Emdoka
John Lijsenstraat 16
B-2321 Hoogstraten
Belgium

Manufacturer responsible for batch release:

Produlab Pharma B.V.
Forellenweg 16
4941 SJ Raamsdonksveer
The Netherlands

Local representatives and contact details to report suspected adverse events:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.