[Version 8.1,01/2017]

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

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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral solution.
Colourless or slightly yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the 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).

4.3 Contraindications

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

4.4 Special warnings for each target species

It is advisable to foresee the appropriate dietary measures.

4.5 Special precautions for use

Special precautions for use in animals
Administration of ranitidine, like all H_2 receptor inhibitors, may promote intragastric bacterial growth by decreasing gastric acidity.
Do not administer to animals with renal or hepatic impairment.

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.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

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.

4.8 Interaction with other medicinal products and other forms of interaction

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

4.9 Amounts to be administered and administration route

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
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			

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

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

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Alimentary tract and metabolism, ranitidine.
ATC vet code: QA02BA02.

5.1 Pharmacodynamic properties

Ranitidine is a competitive antagonist for histamine H_2 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 H_2 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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hypromellose
Ethanol (96%)
Sorbitol liquid non crystallising
Sodium dihydrogen phosphate dihydrate
Sodium phosphate dodecahydrate
Methyl parahydroxybenzoate (E 218)
Propyl parahydroxybenzoate
Sodium hydroxide for pH adjustment
Phosphoric acid for pH adjustment
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: 18 months.
Shelf life after first opening the immediate packaging: 28 days.

6.4. Special precautions for storage

Do not store above 25 °C.
Store in the original container.
Keep the container tightly closed.

6.5 Nature and composition of immediate packaging

The finished product is packed in high density polyethylene bottles of 12ml, 24ml or 48ml with high density polyethylene stoppers and a low density polyethylene plug.
3 ml polypropylene/silicone syringe, graduated every 0.1 ml to 3 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product 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

Emdoka bvba,
John Lijsenstraat 16
B-2321 Hoogstraten
Belgium

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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

10 DATE OF REVISION OF THE TEXT

<{MM/YYYY}>

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

OUTER CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zantoral 30 mg/ml Oral solution for dogs
Ranitidine hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains 30 mg of ranitidine (as ranitidine hydrochloride).

3. PHARMACEUTICAL FORM

Oral solution.

4. PACKAGE SIZE

12 ml
24 ml
48 ml

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Once opened use within 28 days.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.
Store in the original container.
Keep the container tightly closed.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Emdoka bvba,
John Lijsenstraat 16
B-2321 Hoogstraten
Belgium

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BOTTLE (HDPE)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zantoral 30 mg/ml Oral solution for dogs
Ranitidine hydrochloride

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each ml contains 30 mg of ranitidine (as ranitidine hydrochloride).

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

12 ml
24 ml
48 ml

4. ROUTE(S) OF ADMINISTRATION

Oral use.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once opened use within 28 days.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Zantoral 30 mg/ml Oral Solution for Dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Emdoka bvba,
John Lijsenstraat 16
B-2321 Hoogstraten
Belgium

Manufacturer responsible for batch release:
Produlab Pharma B.V.
Forellenweg 16
4941 SJ Raamsdonksveer
Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zantoral 30 mg/ml Oral solution for dogs
Ranitidine hydrochloride

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml of solution contains

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

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

Colourless or slightly yellow solution.

4. INDICATION(S)

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.

6. ADVERSE REACTIONS

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 inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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:

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7.5	0.5 ml / twice daily	30	2.0 ml / twice daily
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10.5	0.7 ml / twice daily	36	2.4 ml / twice daily
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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

Follow the dosing instructions and duration of treatment advised by the veterinary surgeon.

10. WITHDRAWAL PERIOD(S)

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 container: 28 days.

12. SPECIAL WARNING(S)

Special warnings for each target species:
It is advisable to foresee the appropriate dietary measures.

Special precautions for use in animals:
Administration of ranitidine, like all H_2 receptor inhibitors, may promote intragastric bacterial growth by decreasing gastric acidity.
Do not administer to animals with renal or hepatic impairment.

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 drugs that are weak acids, as ranitidine causes a change in gastric pH that may influence bioavailability.

Overdose (symptoms, emergency procedures, 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.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

<{MM/YYYY}>

15. OTHER INFORMATION>

Cardboard box with high density polyethylene bottles of 12ml, 24ml or 48ml.
For animal treatment only. To be supplied only on veterinary prescription.
Not all pack sizes may be marketed.