

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Anthelmin Plus Flavour Tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

Praziquantel	50 mg
Pyrantel embonate	144 mg
Febantel	150 mg

3. PACKAGE SIZE

2 tbl
4 tbl
10 tbl
30 tbl
50 tbl
100 tbl
300 tbl

4. TARGET SPECIES

Dogs (weighing at least 2 kg).



5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

The tablets can be divided into 2 or 4 equal parts.

Dosage:

Body weight	Tablets
2.0 - 2.5 kg	$\frac{1}{4}$
2.6 - 5 kg	$\frac{1}{2}$
5.1 - 7.5 kg	$\frac{3}{4}$
7.6 - 10 kg	1
10.1 - 12.5 kg	1 $\frac{1}{4}$
12.6 - 15 kg	1 $\frac{1}{2}$
15.1 - 17.5 kg	1 $\frac{3}{4}$
17.6 - 20 kg	2
20.1 - 22.5 kg	2 $\frac{1}{4}$
22.6 - 25 kg	2 $\frac{1}{2}$
25.1 - 27.5 kg	2 $\frac{3}{4}$
27.6 - 30 kg	3

Not for use in dogs younger than 2 weeks of age and/or weighing less than 2 kg.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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

KRKA, d.d., Novo mesto

14. MARKETING AUTHORISATION NUMBERS

Vm 01656/4015

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON *SMALL IMMEDIATE PACKAGING UNITS*

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Anthelmin Plus Flavour



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

50 mg/144 mg/150 mg

3. BATCH NUMBER

Lot {number}

3. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Anthelmin Plus Flavour Tablets for dogs

2. Composition

Each tablet contains:

Praziquantel	50 mg
Pyrantel embonate	144 mg
Febantel	150 mg

Yellow coloured, round, biconvex tablets with visible darker spots, cross-scored on one side. The tablets can be divided into 2 or 4 equal parts.

3. Target species

Dogs (weighing at least 2 kg).



4. Indications for use

For the treatment of mixed infections with the following roundworms and tapeworms in adult dogs and puppies:

Nematodes

Ascarids: *Toxocara canis*, *Toxascaris leonina* (late immature forms and mature forms)

Hookworms: *Uncinaria stenocephala*, *Ancylostoma caninum* (adults)

Cestodes

Tapeworms: *Taenia* spp., *Dipylidium caninum*,

5. Contraindications

Do not use simultaneously with piperazine compounds.

Do not exceed the stated dosage when treating pregnant bitches.

Do not use in cases of hypersensitivity to the active substances or to any of the excipients. Do not use in dogs younger than 2 weeks of age and/or weighing less than 2 kg.

6. Special warnings

Special warnings:

Fleas serve as intermediate hosts for one common type of tapeworm – *Dipylidium caninum*. Tapeworm infestation is certain to re-occur unless control of intermediate hosts such as fleas, mice etc. is undertaken.

Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.

Special precautions for safe use in the target species:

Any part-used tablets should be discarded.

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

In the interests of good hygiene, persons administering the tablet directly to a dog or by adding it to the dog's food, should wash their hands afterwards.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or label to the physician.

Pregnancy:

Do not use in bitches during the first two-thirds of pregnancy.

Consult a veterinary surgeon before treating pregnant animals for roundworms.

Lactation:

Can be used during lactation (see "Contraindications" and "Advice on correct administration").

Interaction with other medicinal products and other forms of interaction:

Do not use simultaneously with piperazine as the anthelmintic effects of pyrantel and piperazine (used in many worming veterinary medicinal products for dogs) may be antagonized.

Concurrent use with other cholinergic compounds can lead to toxicity.

Overdose:

Benzimidazoles possess wide safety margin. Pyrantel is not absorbed systematically to any extent. Praziquantel also has a wide safety margin, of up to five times the recommended dose.

7. Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated	Loose stool, diarrhoea, Vomiting.*
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*Transient.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal 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 the 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

For oral use.

The recommended dose rates are: 15 mg/kg bodyweight febantel, 14.4 mg/kg pyrantel and 5 mg/kg praziquantel. This is equivalent to 1 tablet per 10 kg bodyweight.

Tablets may be halved/quartered to allow accuracy of dosing.

The tablet(s) can be given directly to the dog or disguised in food. No restriction of access to food is required either before or after administration of the veterinary medicinal product.

9. Advice on correct administration

To ensure administration of a correct dosage, body weight should be determined as accurately as possible.

Puppies may be wormed with this veterinary medicinal product from 2 weeks of age and every 2 weeks until 12 weeks of age. Thereafter they should be treated at 3 monthly intervals until 6 months of age.

For the control of *Toxocara*, nursing bitches should be dosed 2 weeks after giving birth and every 2 weeks until weaning.

For adult dogs, a single dose should be used. The advice of a veterinarian should be sought regarding the need for and frequency of repeat treatment.

In the event of a heavy roundworm infestation, a repeat dose should be given after 14 days.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton after

{Exp.}. The expiry date refers to the last day of that month.

Shelf life of the divided tablets: use immediately.

Half/quarter tablets should be discarded.

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 not subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 01656/4015

OPA/AI/PVC-AI blister: 2 tablets (1 blister with 2 tablets), in a box.
OPA/AI/PVC-AI blister: 4 tablets (2 blisters with 2 tablets), in a box.
OPA/AI/PVC-AI blister: 10 tablets (1 blister with 10 tablets), in a box.
OPA/AI/PVC-AI blister: 30 tablets (3 blisters with 10 tablets), in a box.
OPA/AI/PVC-AI blister: 50 tablets (5 blisters with 10 tablets), in a box.
OPA/AI/PVC-AI blister: 100 tablets (10 blisters with 10 tablets), in a box.
OPA/AI/PVC-AI blister: 300 tablets (30 blisters with 10 tablets), in a box.
Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse events:

KRKA, d.d., Novo mesto
Smarjeska cesta 6
8501 Novo mesto
Slovenia

Manufacturer responsible for batch release:
KRKA d.d, Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia
KRKA - FARMA d.o.o., V. Holjevca 20/E, 10450 Jastrebarsko, Croatia

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.

17. Other information

Gavin Hall
Approved: 04 March 2026