

**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 XL Tablets

**2. STATEMENT OF ACTIVE**

Each tablet contains:

Praziquantel	175 mg
Pyrantel embonate	504 mg
Febantel	525 mg

**3. PACKAGE SIZE SUBSTANCES**

2 tbl  
4 tbl  
10 tbl  
12 tbl  
24 tbl  
30 tbl  
50 tbl  
60 tbl  
100 tbl  
102 tbl

**4. TARGET SPECIES**

Dogs (weighing at least 17.5 kg).



**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

Oral use.  
The tablets can be divided into equal halves.

Dosage:

Body weight	Tablets
17.5 kg	1/2
17.6 - 35 kg	1
35.1 - 52.5 kg	1 1/2
52.6 - 70 kg	2

This product is not recommended for use in dogs under 17.5 kg body weight.

**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 01656/4016

**15. BATCH NUMBER**

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON *SMALL IMMEDIATE PACKAGING UNITS***

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Anthelmin Plus XL



**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

175 mg/504 mg/525 mg

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

## **B. PACKAGE LEAFLET**

## 1. Name of the veterinary medicinal product

Anthelmin Plus XL Tablets for dogs

## 2. Composition

Each tablet contains:

Praziquantel	175 mg
Pyrantel embonate	504 mg
Febantel	525 mg

Oval, biconvex tablets with beveled edges and scored on both sides. Slightly greenish-yellow. The tablets can be divided into equal halves.

## 3. Target species

Dogs (weighing at least 17.5 kg).



## 4. Indications for use

For the treatment of mixed infections with the following roundworms and tapeworms in adult dogs: 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 use in cases of hypersensitivity to the active substance or to any of excipients. Do not exceed the stated dosage when treating pregnant bitches.

## 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:

This veterinary medicinal product is not recommended for use in dogs under 17.5 kg bodyweight. 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 the 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:

Veterinary medicinal product is well tolerated in dogs. In safety studies of up to five times the recommended dose gave rise to occasional vomiting.

## **7. Adverse events**

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 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 35 kg bodyweight.

Tablets may be halved to allow accuracy of dosing.

No restriction of access to food is required either before or after administration of the veterinary medicinal product.

The tablet(s) can be given directly to the dog or disguised in food.

## **9. Advice on correct administration**

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

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

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

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.

## **10. Withdrawal periods**

Not applicable.

## **11. Special storage precautions**

Keep out of the sight and reach of children.

This veterinary 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 01656/4016

OPA/Al/PVC-Al blister

Cardboard box containing 2, 4, 10, 12, 24, 30, 50, 60, 100 or 102 tablets.

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](http://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 - FARMA d.o.o., V. Holjevca 20/E, 10450  
Jastrebarsko, Croatia  
KRKA, d.d., Novo mesto, Šmarješka  
cesta 6, 8501 Novo mesto, Slovenia

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