PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Anthelmin Plus XL Tablets for dogs

Praziquantel, pyrantel embonate, febantel

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains:
Active substances:

Praziquantel	175 mg
Pyrantel embonate	504 mg
Febantel	525 mg

3. PHARMACEUTICAL FORM

Tablets
The tablets can be divided into equal halves.

4. PACKAGE SIZE

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

5. TARGET SPECIES

Dogs(large and extra large size)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

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

Dispose of waste material in accordance with local requirements.

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

For animal treatment only.

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

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

16. MARKETING AUTHORISATION NUMBER

Vm 01656/4016

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Anthelmin Plus XL Tablets for dogs

Praziquantel, pyrantel embonate, febantel

2. NAME OF THE MARKETING AUTHORISATION HOLDER

KRKA

3. EXPIRY DATE

EXP:

4. BATCH NUMBER

Lot:

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET FOR:

Anthelmin Plus XL Tablets 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:
KRKA d.d, Novo mesto, Šmarješka 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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Anthelmin Plus XL Tablets for dogs

Praziquantel, pyrantel embonate, febantel

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

Each tablet contains:
Active substances:

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.

4. INDICATION(S)

For the treatment of mixed infestations 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 animals with a known hypersensitivity to the active substance or to any of excipients.

Do not exceed the stated dosage when treating pregnant bitches.

6. ADVERSE REACTIONS

None known.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs (large and extra large size)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral administration.

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 .

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

9. ADVICE ON CORRECT ADMINISTRATION

To ensure administration of a correct dose, 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 PERIOD

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.

12. SPECIAL WARNING(S)

Special warnings for each target species:
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 use in animals:
This 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 and show the package leaflet to the physician.

Use during pregnancy, lactation or lay:
Consult a veterinary surgeon before treating pregnant animals for roundworms.
The product may be used during lactation.
Do not use in bitches during the first two-thirds of pregnancy.

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 products for dogs) may be antagonized.
Concurrent use with other cholinergic compounds can lead to toxicity.

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

Medicines should not be disposed of via wastewater. Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

OPA/Al/PVC-Al blister: 2 tablets (1 blister with 2 tablets), in a box.
OPA/Al/PVC-Al blister: 4 tablets (2 blisters with 2 tablets), in a box.

OPA/Al/PVC-Al blister: 10 tablets (1 blister with 10 tablets), in a box.
OPA/Al/PVC-Al blister: 12 tablets (2 blisters with 6 tablets), in a box.
OPA/Al/PVC-Al blister: 24 tablets (4 blisters with 6 tablets), in a box.
OPA/Al/PVC-Al blister: 30 tablets (3 blisters with 10 tablets or 5 blisters with 6 tablets), in a box.
OPA/Al/PVC-Al blister: 50 tablets (5 blisters with 10 tablets), in a box.
OPA/Al/PVC-Al blister: 60 tablets (10 blisters with 6 tablets or 6 blisters with 10 tablets), in a box.
OPA/Al/PVC-Al blister: 100 tablets (10 blisters with 10 tablets), in a box.
OPA/Al/PVC-Al blister: 102 tablets (17 blisters with 6 tablets), in a box.
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.
NFA-VPS
Vm 01656/4016
For animal treatment only.

Local representative:
KRKA UK Ltd
United Kingdom
Tel: 02071 646 156
pharmacovigilance.uk@krka.biz

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