PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Krka Roundworm and Tapeworm Wormer 50/144/150 mg Tablets for Dogs
Praziquantel, pyrantel embonate, febantel

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Active substances:

Praziquantel	50 mg
Pyrantel embonate	144 mg
Febantel	150 mg

3. PHARMACEUTICAL FORM

Tablets
The tablets can be divided into halves or quarters.

4. PACKAGE SIZE

2 tablets
4 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

FOR THE TREATMENT OF ROUNDWORMS, HOOKWORMS AND TAPEWORMS

For the treatment of mixed infestations with roundworms, hookworms 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*

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use.
1 tablet per 10 kg body weight.

Dosage:
15 mg, febantel, 14.4 mg pyrantel and 5 mg praziquantel per kg of body weight.

Body weight	Tablets
2 kg -2.5 kg	¼ tablet
2.5 kg -5 kg	½ tablet
5 kg - 7.5 kg	¾ tablet
7.5 kg - 10 kg	1 tablet
10 kg - 15 kg	1 ½ tablets
15 kg - 20 kg	2 tablets
20 kg - 25 kg	2 ½ tablets
25 kg - 30 kg	3 tablets
30 kg - 35 kg	3 ½ tablets
35 kg - 40 kg	4 tablets

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.

AVM-GSL

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 01656/5004

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Krka Roundworm and Tapeworm Wormer 50/144/150 mg 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:

Krka Roundworm and Tapeworm Wormer 50/144/150 mg 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
Šmarkeška 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

Krka Roundworm and Tapeworm Wormer 50/144/150 mg Tablets for Dogs
Praziquantel, pyrantel embonate, febantel

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

Each tablet contains:
Active substances:

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 halves or quarters.

4. INDICATION(S)

For the treatment of mixed infestations 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 bitches during the first two-thirds of pregnancy.
Do not use in animals with a known hypersensitivity to the active substance or to any of the excipients.

Do not use in dogs younger than 2 weeks of age and/or weighing less than 2 kg.
Do not use simultaneously with other deworming products without veterinary advice.

6. ADVERSE REACTIONS

In very rare cases transient loose faeces, diarrhoea and/or vomiting may occur.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

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

7. TARGET SPECIES

Dogs (small and medium size)

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

For oral administration.
It is important to follow the treatment recommendations as presented here. Do not deviate from the recommendations without the advice of your veterinary surgeon.

The recommended dose rates are: 15 mg/kg body weight febantel, 14.4 mg/kg pyrantel and 5 mg/kg praziquantel. This is equivalent to 1 tablet per 10 kg body weight.
Tablets may be halved/quartered to allow accuracy of dosing.

Body weight	**Tablets**
Over 2 kg up to 2.5 kg	¼ tablet
Over 2.5 kg up to 5 kg	½ tablet
Over 5 kg up to 7.5 kg	¾ tablet
Over 7.5 kg up to 10 kg	1 tablet
Over 10 kg up to 15 kg	1 ½ tablets
Over 15 kg up to 20 kg	2 tablets
Over 20 kg up to 25 kg	2 ½ tablets
Over 25 kg up to 30 kg	3 tablets
Over 30 kg up to 35 kg	3 ½ tablets
Over 35 kg up to 40 kg	4 tablets

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 product.

9. ADVICE ON CORRECT ADMINISTRATION

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

Puppies may be wormed with this 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. It is advisable to treat the bitch at the same time as the puppies.
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.

10. WITHDRAWAL PERIOD

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.

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.
Dogs may become infected with worms by eating insects (including fleas and lice), birds, small rodents, rabbits or raw offal from affected sheep, goats and cattle. Dogs will continue to be re-infected unless the route of infection is controlled e.g. treating a flea infestation or preventing a dog from scavenging or hunting.
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:
Any part-used tablets should be discarded.
Not for use in dogs younger than 2 weeks and/or weighing less than 2 kg.
Do not exceed the stated dose, especially when treating pregnant bitches.
In dogs less than 6 weeks old, tapeworm infections are highly uncommon. Treatment of animals less than 6 weeks old with a fixed combination product against cestodes and nematodes may, therefore, not be necessary.
To minimise the risk of reinfestation and new infestation, excreta should be collected and properly disposed of for 24 hours following treatment.

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.
Any unused or part used tablets should be disposed of safely.
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.
The tablets 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 antagonised.

Concurrent use with other cholinergic compounds can lead to toxicity.
Simultaneous administration of compounds that inhibit the activity of acetylcholinesterase - AChE (e.g.organophosphates) may increase systemic effects of pyrantel.
Plasma concentrations of praziquantel may be decreased by concomitant administration with drugs that increase the activity of cytochrome P-450 enzymes (e.g. dexamethasone, phenobarbital).

Overdose (symptoms, emergency procedures, antidotes), if necessary:
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.

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

Medicines should not be disposed of via wastewater. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2023

15. OTHER INFORMATION

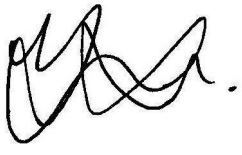
OPA/Al/PVC-Al blister: 2 tablets (1 blister with 2 tablets), in a box.
OPA/Al/PVC-Al blister: 4 tablets (2 blisters with 2 tablets), in a box.

Not all pack sizes may be marketed.

For animal treatment only.

AVM-GSL

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



Approved: 22 February 2024