SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Krka Wormer 50/144/150 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:

Praziquantel	50 mg
Pyrantel embonate	144 mg
Febantel	150 mg

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.
Yellow coloured, round, biconvex tablets with visible darker spots, cross-scored on one side.
The tablets can be divided into halves or quarters.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs (small and medium size)

4.2 Indications for use, specifying the target species

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*

4.3 Contraindications

Do not use simultaneously with piperazine compounds.
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.

4.4 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.

4.5 Special precautions for use

Special precautions for use in animals
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, any excreta within 24 hours following treatment should be collected and properly disposed of.

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 tablets or part tablets should be disposed of safely.
In case of accidental ingestion, seek medical advice and show the package leaflet to the physician.

4.6 Adverse reactions (frequency and seriousness)

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).

4.7 Use during pregnancy, lactation or lay

Consult a veterinary surgeon before treating pregnant animals.
The tablets may be used during lactation (see Section 4.9).
Do not use in bitches during the first two-thirds of pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

Do not combine 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.
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).

4.9 Amounts to be administered and administration route

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.

Dosage
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

Administration and Duration of Treatment
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.
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.

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

Benzimidazoles possess a 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.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, Benzimidazoles and related substances
ATCVet code: QP52AC55

5.1 Pharmacodynamic properties

The product contains anthelmintics active against roundworms and tapeworms. The product contains three active substances: febantel, pyrantel embonate (pamoate) and praziquantel, a partially hydrogenated pyrazino-isoquinoline derivative used widely as an anthelmintic for both human and veterinary use. Pyrantel acts as a cholinergic agonist. Its mode of action is to stimulate nicotinic cholinergic receptors of the parasite, induce spastic paralysis and thereby allow removal from the gastro-intestinal (GI) system by peristalsis.
With the mammalian system febantel undergoes ring closure forming fenbendazole and oxfendazole. It is these chemical entities which exert the anthelmintic effect by inhibition of tubulin polymerisation. Formation of microtubules is thereby prevented, resulting in disruption to structures vital to the normal functioning of the helminth. Glucose uptake, in particular, is affected, leading to depletion in cell ATP. The parasite dies upon exhaustion of its energy reserves, which occurs 2 – 3 days later.
Praziquantel is very rapidly absorbed and distributed throughout the parasite. Both *in vitro* and *in vivo* studies have shown that praziquantel causes severe damage to the parasite integument, resulting in contraction and paralysis. There is an almost instantaneous tetanic contraction of the parasite musculature and a rapid vacuolisation of the syncytial tegument. This rapid contraction has been explained by changes in divalent cation fluxes, especially calcium.

In this fixed combination product pyrantel and febantel act synergistically against nematodes (ascarids and hookworms) in dogs. In particular, the activity spectrum covers *Toxocara canis*, *Toxascaris leonina*, *Uncinaria stenocephala* and *Ancylostoma caninum*. The spectrum of activity of praziquantel covers also cestode species in dogs, in particular all *Taenia* spp. and *Dipylidium caninum*. Praziquantel acts against adult and immature forms of these parasites.

5.2 Pharmacokinetic particulars

Perorally administered praziquantel is absorbed almost completely from the intestinal tract. After absorption, the drug is distributed to all organs. Praziquantel is metabolised into inactive forms in the liver and secreted in bile. It is excreted within 24 hours to more than 95% of the administered dosage. Only traces of non-metabolised praziquantel are excreted.
The pamoate salt of pyrantel has low aqueous solubility, an attribute that reduces absorption from the gut and allows the drug to reach and be effective against

parasites in the large intestine. Because of the low systemic absorption of pyrantel pamoate, there is very little danger of adverse reactions/toxicity in the host. Following absorption, pyrantel pamoate is quickly and almost completely metabolized into inactive metabolites that are excreted rapidly in the urine.

Febantel is absorbed relatively rapidly and metabolized to a number of metabolites including fenbendazole and oxfendazole, which have anthelmintic activity.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose Monohydrate
Maize Starch
Povidone K-30
Sodium Lauryl Sulfate
Microcrystalline Cellulose
Colloidal Anhydrous Silica
Magnesium Stearate
Meat Flavour

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Any part-used tablets should be discarded.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

OPA/Al/PVC-Al blister
Cardboard box containing 2 or 4 tablets.
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

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

8. MARKETING AUTHORISATION NUMBER

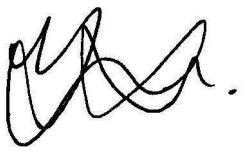
Vm 01656/3002

9. DATE OF FIRST AUTHORISATION

26 July 2022

10. DATE OF REVISION OF THE TEXT

November 2023



Approved: 08 March 2024