SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Endogard Plus Flavour Tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:

Praziquantel	50 mg
Pyrantel embonate	144 mg
Febantel	150 mg

Excipients:

Qualitative composition of excipients and other constituents
Lactose Monohydrate
Maize Starch
Povidone K-30
Sodium Lauryl Sulfate
Microcrystalline Cellulose
Colloidal Anhydrous Silica
Magnesium Stearate
Meat Flavour

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. CLINICAL INFORMATION

3.1 Target species

Dogs (small and medium size).

3.2 Indications for use for each target species

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*

3.3 Contraindications

Do not use simultaneously with piperazine compounds.
Do not exceed the stated dosage when treating pregnant bitches.
Do not use in 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.

3.4 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.

3.5 Special precautions for use

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 and show the package leaflet to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):	Loose stool[1], diarrhoea[1,2], vomiting[1,2]

[1]In puppies: transient.
[2]In adult dogs: very rare cases of vomiting, with or without diarrhoea.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for contact details.

3.7 Use during pregnancy, lactation or lay

Consult a veterinary surgeon before treating pregnant animals for roundworms.
The product may be used during lactation (see Sections 3.3 and 3.9).
Do not use in bitches during the first two-thirds of pregnancy.

3.8 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.

3.9 Administration routes and dosage

For oral administration.

Dosage
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.

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 a correct dosage, 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. 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 routine control a single dose is recommended at 3 monthly intervals.
In the event of a heavy roundworm infestation, a repeat dose should be given after 14 days.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal period

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP52AC55

4.2 Pharmacodynamics

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 polymerization. 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 all relevant 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 praziquntel covers also cestode species in dogs, in particular all *Taenia* spp.and *Dipylidium caninum*,. Praziquantel acts against adult and immature forms of these parasites.

4.3 Pharmacokinetics

Perorally administered praziquantel is absorbed almost completely from the intestinal tract. After absorption, the drug is distributed to all organs. Praziquantel is metabolized 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

Nature of container: Print and perforated Alu-Alu blister: 2 tablets (1 blister with 2 tablets), in a box.
Print and perforated Alu-Alu blister: 4 tablets (2 blisters with 2 tablets), in a box.
Print and perforated Alu-Alu blister: 10 tablets (1 blister with 10 tablets), in a box.
Print and perforated Alu-Alu blister: 30 tablets (3 blisters with 10 tablets), in a box.
Print and perforated Alu-Alu blister: 50 tablets (5 blisters with 10 tablets), in a box.
Print and perforated Alu-Alu blister: 100 tablets (10 blisters with 10 tablets), in a box.
Print and perforated Alu-Alu blister: 300 tablets (30 blisters with 10 tablets), in a box.
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

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.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

KRKA, d.d., Novo mesto

7. MARKETING AUTHORISATION NUMBER

Vm 01656/4017

8. DATE OF FIRST AUTHORISATION

02 June 2011

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

September 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product not subject to prescription.

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

Gavin Hall
Approved: 14 March 2025