SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canihelmin plus 50 mg/144 mg/150 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 tablet contains:

Active substances:
Praziquantel 50 mg
Pyrantel Embonate 144 mg
(equivalent to 50 mg of pyrantel)
Febantel 150 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet.
The tablet is yellow, round, flat tablet with a cross groove on one side.
The tablet can be subdivided into quarters.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

Treatment of mixed infections by nematodes and cestodes of the following species:

Nematodes:
Ascarids: *Toxocara canis*, *Toxascaris leonina* (adults).
Hookworms: *Uncinaria stenocephala*, *Ancylostoma caninum* (adults).
Whipworms: *Trichuris vulpis* (adults).

Cestodes:
Tapeworms: *Echinococcus* spp (*Echinococcus granulosus, Echinococcus multilocularis*), *Taenia* spp. (*Taenia hydatigena, Taenia pisiformis, Taenia taeniaeformis*), *Dipylidium caninum* (adults).

4.3 Contraindications

Do not use simultaneously with piperazine compounds.

Do not use in known cases of hypersensitivity to the active substances or to any of the excipients.

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 reoccur unless control of intermediate hosts such as fleas, mice, etc. is undertaken.
Tapeworm infestation is unlikely in pups less than 6 weeks of age.
Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy.
Strategies that should be avoided because they might lead to an increased risk of development of resistance to anthelmintic drugs include:
- Too frequent and repeated use of anthelmintics from the same class over an extended period of time
- Underdosing

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

4.5 Special precautions for use

Special precautions for use in animals

To ensure administration of a correct dose, body weight should be determined as accurately as possible. Not for use in dogs younger than 2 weeks of age and/or weighing less than 3 kg.
Any unused subdivided tablet should be discarded.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Avoid contact with the eyes. In case of eye contact, rinse abundantly with water.
Avoid hand-to-eye and hand-to-mouth contact while handling the product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

In very rare cases, gastrointestinal disorders (diarrhoea, emesis) have been observed.

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

4.7 Use during pregnancy, lactation or lay

Pregnancy:
Teratogenic effects attributed to high doses of febantel have been reported in sheep and rats. No studies have been performed in dogs during early pregnancy. Use of the product during pregnancy should be in accordance with the benefit risk assessment by the responsible veterinarian.
Bitches should not be treated in the first 40 days of pregnancy.
Do not exceed the stated dose when treating pregnant bitches.

4.8 Interaction with other medicinal products and other forms of interaction

Concurrent use with other cholinergic compounds can lead to toxicity.

This product should not be administered at the same time as other drugs with cholinergic effect.

Simultaneous administration of compounds that inhibit the activity of acetylcholinesterase - AChE (e.g.organophosphates) may increase systemic effects of pyrantel.

Do not use simultaneously with piperazine compounds as anthelmintic effects of pyrantel and piperazine may be antagonised.

4.9 Amounts to be administered and administration route

Oral use.
This product can be given directly to the dog or disguised in food (in piece of meat, cheese etc.). It is recommended to treat animals before feeding and no fasting is needed before or after treatment.

The recommended dose rate is 1 tablet per 10 kg BW in a single dose (5 mg praziquantel, 15 mg febantel and 14.4 mg pyrantel embonate, per kg BW). To ensure a correct dosage, body weight should be determined as accurately as possible.

Puppies and small dogs

3-5 kg BW	1/2 tablet
> 5-10 kg BWht	1 tablet

Medium dogs

> 10-20 kg BW	2 tablets
> 20-30 kg BW	3 tablets

Large dogs
> 30-40 kg BW 4 tablets

If there is a risk of re-infestation the advice of a veterinarian should be sought regarding the need for, and the frequency of, repeat administration.

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

The combination of praziquantel, pyrantel embonate and febantel is well tolerated in dogs. In safety studies a single dose of 5 times the recommended dose, or greater, gave rise to occasional vomiting.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintic, praziquantel combinations.
ATCvet code: QP52AA51

5.1 Pharmacodynamic properties

This product contains anthelmintics active against gastrointestinal roundworms and tapeworms. The product contains three active substances, as follows:

1. Febantel, a probenzimidazole
2. Pyrantel embonate (pamoate), a tetrahydropyrimidine derivative
3. Praziquantel, a partially hydrogenated pyrazinoisoquinoline derivative

In this fixed combination, pyrantel and febantel act against all relevant nematodes (ascarids, hookworms and whipworms) in dogs. In particular, the activity spectrum covers *Toxocara canis*, *Toxascaris leonina*, *Uncinaria stenocephala*, *Ancylostoma caninum* and *Trichuris vulpis*.

This combination shows synergistic activity in the case of hookworms and febantel is effective against *T. vulpis*.
The spectrum of activity of praziquantel covers all important cestode species in dogs, in particular *Taenia* spp., *Dipylidium caninum*, *Echinococcus granulosus* and *Echinococcus multilocularis*. Praziquantel acts against all adult and immature forms of these parasites.

Praziquantel is a synthetic isoquinolinepyrazine derivate. It induces a rapid and sustained paralytic muscle contraction of the parasite and tegumental disruption. The contraction of parasite musculature is the primary effect which is followed by a rapid vacuolisation of the syncytial tegument. Muscular contraction and tegumental disruption are followed by exposure of parasite antigens, binding, and penetration of host immune cells into the parasite.

Pyrantel is a tetrahydropyrimidine compound and acts selectively as an agonist at synaptic and extrasynaptic nicotinic acetylcholine receptors on nematode muscle cells to produce contraction and spastic paralysis.

Febantel is a pro-benzimidazole compound and its spectrum depends on its main active metabolites fenbendazole and oxfendazole. The benzimidazole and pro-benzimidazole pharmacological activity is based on the binding to parasite tubulin, which produces subsequent disruption of the tubulin-microtubule dynamic equilibrium.

5.2 Pharmacokinetic particulars

Praziquantel is quantitatively and rapidly absorbed and metabolized by all species. All species excrete the parent compound and its metabolites rapidly; within 24 hours after administration of radiolabelled compound the radioactivity in the serum was of the same order of magnitude as the detection limit. Renal excretion is the main route of elimination of praziquantel and its metabolites.

The pyrantel embonate salt is poorly absorbed from the GI tract and the absorbed drug is rapidly metabolized and excreted into the faeces. The entire radioactivity administered was excreted within 96 hours. The dog is the only species excreting a larger proportion of the drug/ metabolites in urine compared to faeces.

Febantel is absorbed from the intestinal tract, metabolized in the liver, and eliminated up to 70% in the bile at a half-life of 9 h in rats. Febantel is quickly metabolized to fenbendazole. Absorption of febantel was reported to be moderate in the rat with around 25-30% of the oral dose excreted in the urine, although 70% biliary excretion after parenteral dosing suggests the initial absorption after oral administration may be higher.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Maize starch
Copovidone
Sodium laurilsulfate
Cellulose microcrystalline
Silica, colloidal anhydrous
Hydrogenated vegetable oil, type I
Talc
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years .
Shelf life of the divided tablets: use immediately.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

The product is presented in Al-PE/Al-PE strip printed on one side. 2 strips x 10 tablets or 10 strips x 10 tablets are placed in a paper box.

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

GENERA Inc.
Svetonedeljska cesta 2
Kalinovica
10436 Rakov Potok
Croatia

8. MARKETING AUTHORISATION NUMBER

Vm 43676/4001

9. DATE OF FIRST AUTHORISATION

07 July 2016

10. DATE OF REVISION OF THE TEXT

July 2020

PROHIBITION OF SALE, SUPPLY AND/OR USE

For animal treatment only. To be supplied only on veterinary prescription.

Approved 21 July 2020