ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{BOX/PAPER}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canihelmin plus 50 mg/144 mg/150 mg tablets for dogs
Praziquantel, pyrantel embonate, febantel

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

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

3. PHARMACEUTICAL FORM

Tablet.

4. PACKAGE SIZE

2 x 10 tablets.
10 x 10 tablets.

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

7. METHOD AND ROUTE OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life of the divided tablets: use immediately.

11. SPECIAL STORAGE CONDITIONS

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

Disposal: read package leaflet.

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

For animal treatment only. To be supplied only on veterinary prescription.
POM–V

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

GENERA Inc.
Svetonedeljska cesta 2
Kalinovica
10436 Rakov Potok
Croatia

16. MARKETING AUTHORISATION NUMBER(S)

Vm 43676/4001

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{STRIPS/AL/PE FOIL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canihelmin plus 50 mg/144 mg/150 mg tablets for dogs
Praziquantel, pyrantel embonate, febantel

2. NAME OF THE MARKETING AUTHORISATION HOLDER

GENERA

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.
POM-V

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Canihelmin plus 50 mg/144 mg/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 and manufacturer responsible for batch release
GENERA Inc.
Svetonedeljska cesta 2
Kalinovica
10436 Rakov Potok
Croatia

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canihelmin plus 50 mg/144 mg/150 mg tablets for dogs
Praziquantel, pyrantel embonate, febantel

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Each tablet contains:

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

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

4. INDICATIONS

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).

5. 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.

6. ADVERSE REACTIONS

In very rare cases, gastrointestinal disorders (diarrhoea, emesis) have been observed.If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.
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 treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

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

Oral use.
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 BW	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.

9. ADVICE ON CORRECT ADMINISTRATION

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.

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 {month/year}.
The expiry date refers to the last day of that month.

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

12. SPECIAL WARNINGS

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.

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.
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.

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 effects.

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.

Overdose (symptoms, emergency procedures, antidotes):

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.

Incompatibilities:

Not applicable.

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

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2020

15. OTHER INFORMATION

For animal treatment only. To be supplied only on veterinary prescription.
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Pack sizes:
2 x 10 tablets.
10 x 10 tablets.
Not all pack sizes may be marketed.

Approved 21 July 2020