[Version 8.1, 01/2017]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:
Praziquantel 50 mg
Pyrantel 50 mg
(equivalent to 144 mg of pyrantel embonate)
Febantel 150 mg
Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.
Yellow, round, flat tablets scored with a cross on one side allowing subdivision into equal quarters

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

In dogs: treatment of mixed infections by nematodes and cestodes of the following species:

Nematodes:
Ascarids: *Toxocara canis, Toxascaris leonina* (adult and late immature forms).
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* (adult and immature forms).

4.3 Contraindications

Do not use simultaneously with piperazine compounds.
Do not use in case 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 re-occur unless control of intermediate hosts such as fleas, mice, etc. is undertaken.
Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.
Tapeworms are unlikely in pups less than 6 weeks of age.

4.5 Special precautions for use

Special precautions for use in animals

Any part used tablet should be discarded.

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

Avoid skin and eye contact. If contact occurs, wash the product from skin or eyes immediately with water.
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)

None known.

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 a benefit risk assessment by the responsible veterinarian. It is recommended that the product is not used in dogs during the first 4 weeks 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.

Simultaneous administration of compounds that inhibit the activity of AChE (organophosphates) may increase of systemic effect 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.

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

This product can be given directly to the dog or disguised in food (into a 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 rates are: 1 tablet per 10 kg BW in a single dose (5 mg praziquantel, 15mg febantel and 14.4 mg pyrantel embonate, per kg BW).

Puppies and small dogs

0,5- 2 kg BW	1/4 tablet
2-5 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 for 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 vacuolization 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 tetrahydropyrimidine compound and acts selectively as agonists at synaptic and extrasynaptic nicotinic acetylcholine receptors on nematode muscle cells and produce contraction and spastic paralysis.

Febantel is a pro-benzimidazole compound, and its spectrum depends on its main active metabolites fenbendazole and oxfendazole. The BZD and pro-BZD 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 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% - by 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 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Discard any unused subdivided tablet.

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 of 10 tablets or 10 strips of 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

Laboratorios Syva S.A.U.
Avda. Párroco Pablo Díez, 49-57
24010 León (Spain)

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<Date of first authorisation:> <{DD/MM/YYYY}><{DD month YYYY}>
<Date of last renewal:> <{DD/MM/YYYY}><{DD month YYYY}>

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

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

As a national issue (Spain): To be administered by the veterinarian or under veterinarian supervision.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{BOX/PAPER}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE

Each tablet contains:

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

3. PHARMACEUTICAL FORM

Tablets.

4. PACKAGE SIZE

2 strips x 10 tablets.
10 strips 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}

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.
National issue (Spain): Administration by a veterinary surgeon or under their direct responsibility.

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

Laboratorios Syva S.A.U.
Avda. Párroco Pablo Díez, 49-57
24010 León (Spain)

16. MARKETING AUTHORISATION NUMBER(S)

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

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

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Laboratorios Syva S.A.U.

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Canitenol 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
Laboratorios Syva S.A.U.
Avda. Párroco Pablo Díez, 49-57
24010 León (Spain)

Manufacturer responsible for batch release
GENERA Inc.
Svetonedeljska 2, Kalinovica
10436 Rakov Potok (Croatia)

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canitenol 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	50 mg
(equivalent to pyrantel embonate	144 mg)
Febantel	150 mg

Yellow, round, flat tablets scored with a cross on one side allowing subdivision into equal quarters.

4. INDICATIONS

In dogs: treatment of mixed infections by nematodes and cestodes of the following species:

Nematodes:
Ascarids: *Toxocara canis, Toxascaris leonina* (adult and late immature forms).
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* (adult and immature forms).

5. CONTRAINDICATIONS

Do not use simultaneously with piperazine compounds.
Do not use in case of hypersensitivity to the active substances or to any of the excipients.

6. ADVERSE REACTIONS

None known.
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.

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

The recommended dose rates are: 1 tablet per 10 kg BW in a single dose (5 mg praziquantel, 15mg febantel and 14.4 mg pyrantel embonate, per kg BW).

Puppies and small dogs
0,5- 2 kg BW 1/4 tablet
2-5 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 for 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 (into a 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}.

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life of the subdivided 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.
Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.
Tapeworms are unlikely in pups less than 6 weeks of age.

Special precautions for use in animals:

Any part used tablet should be discarded

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

Avoid skin and eye contact. If contact occurs, wash the product from skin or eyes immediately with water.
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 a benefit risk assessment by the responsible veterinarian. It is recommended that the product is not used in dogs during the first 4 weeks 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.

Simultaneous administration of compounds that inhibit the activity of AChE (organophosphates) may increase of systemic effect 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

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon or pharmacist 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

15. OTHER INFORMATION

For animal treatment only. To be supplied only on veterinary prescription.
As a national issue (Spain): To be administered by the veterinarian or under veterinarian supervision.