B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

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.

3. Target species

Dogs

4. Indications for use

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 cases of hypersensitivity to the active substances or to any of the excipients.

6. Special warnings

Special warnings:

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 safe use in the target species:

Any part used tablet should be discarded

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

People with known hypersensitivity to any of active substances should avoid contact with the veterinary medicinal product.

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:

Laboratory studies with high doses of febantel in sheep and rats have shown evidence of teratogenic effects. No studies have been performed in dogs during early pregnancy. Use only according to the 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:

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.

Special restrictions for use and special conditions for use:

[To be completed in accordance with national requirements after conclusion of the /DCP.]

7. Adverse events

None known

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system (national system details).

8. Dosage for each species, routes and method of administration

Oral use

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

To ensure a correct dosage, 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.

10. Withdrawal periods

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. The expiry date refers to the last day of that month.

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life of the subdivided tablets: use immediately.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater <or household waste>.

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.

Ask your <veterinary surgeon> < or pharmacist> how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Package sizes:
Paper box containing 2 strips of 10 tablets
Paper box containing 10 strips of 10 tablets

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder:
Laboratorios Syva S.A.
Calle Marqués de la Ensenada, 16
28004 MADRID
ESPAÑA

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

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Local representatives and contact details to report suspected adverse reactions:

España
Contact details to report suspected adverse reactions:
Laboratorios Syva S.A.
Parque Tecnológico de León
Calle Nicostrato Vela M15-M16
24009 LEÓN
ESPAÑA
Tel: + 34 987 800 800
E-mail: farmacovigilancia@syva.es

Portugal
Contact details to report suspected adverse reactions:
Laboratorios Syva S.A.
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