LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Wellplus Flavoured Tablets for Dogs
Praziquantel, pyrantel embonate, febantel

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains:

Praziquantel	50 mg
Pyrantel embonate	144 mg
Febantel	150 mg

3. PHARMACEUTICAL FORM

Tablets
The tablets can be divided into two or four equal parts..

4. PACKAGE SIZE

2 tablets
10 tablets
20 tablets
50 tablets
100 tablets
300 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Shelf-life after first opening the immediate packaging: 15 days
Shelf-life after dividing the tablet into halves or quarters: 15 days

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.

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

DIVASA - FARMAVIC, S.A.
Ctra. Sant Hipòlit, km 71
08503 GURB - VIC
Barcelona, Spain

16. MARKETING AUTHORISATION NUMBER(S)

Vm 33229/4003

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Wellplus Flavoured Tablets for Dogs
Praziquantel, pyrantel embonate, febantel

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Divasa-Farmavic S.A.

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

<Batch> <Lot> <BN> {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Wellplus Flavoured 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:
Divasa-Farmavic S.A.
Ctra. Sant Hipòlit, km 71
08503 GURB - VIC
Barcelona, Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Wellplus Flavoured Tablets for Dogs
Praziquantel, pyrantel embonate, febantel

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each tablet contains:

Praziquantel	50 mg
Pyrantel embonate	144 mg
Febantel	150 mg

Yellowish round tablets with brown dots.
The tablets can be divided into two or four equal parts

4. INDICATION(S)

For the treatment of mixed infestations with the following roundworms and tapeworms in dogs and puppies:
Ascarids: *Toxocara canis*, *Toxascaris leonina* (adult and late immature forms)
Hookworms: *Uncinaria stenocephala*, *Ancylostoma caninum* (adults)
Tapeworms: *Echinococcus granulosus*, *Echinococcus multilocularis*, *Dipylidium caninum*, *Taenia* spp., *Multiceps multiceps* (adult and immature forms)

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

In very rare cases slight and transient digestive tract disorders such as vomiting and/or diarrhoea may occur. In individual cases these signs can be accompanied by nonspecific signs such as lethargy, anorexia or hyperactivity".

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- 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 serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

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

Oral use.

Dosage
The recommended dose rates are: 15 mg febantel, 14.4 mg pyrantel embonate and 5 mg praziquantel per kg bodyweight. This is equivalent to 1 tablet per 10 kg bodyweight.
Tablets may be halved/quartered as required.

For example, a dog weighing
- 2.5 kg bodyweight receives ¼ of the tablet
- 5.0 kg bodyweight receives ½ of the tablet
- 10 kg bodyweight receives 1 tablet
- 15 kg bodyweight receives 1 ½ tablets
- 20 kg bodyweight receives 2 tablets
- 30 kg bodyweight receives 3 tablets
etc.

Puppies should be treated at 2 weeks of age and every 2 weeks until 12 weeks of age. Thereafter they should be treated at 3 month intervals. It is advisable to treat the bitch at the same time as the puppies. Not for use in dogs weighing less than 2.5 kg.
For routine worm control adult dogs should be treated every 3 months. For routine treatment a single dose is recommended. In the event of heavy roundworm infestation a repeat dose should be given after 14 days.

9. ADVICE ON CORRECT ADMINISTRATION

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

The tablets can be given directly to the dog or disguised in food. No starvation is needed before or after treatment.

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.

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 label and carton after EXP. The expiry date refers to the last day of that month. Return any part tablet to the opened blister pack.

Shelf-life after first opening the immediate packaging: 15 days
Shelf-life after dividing the tablet into halves or quarters: 15 days

12. SPECIAL WARNING(S)

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.

User warnings

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.

Echinococcosis represents a hazard for humans. As Echinococcosis is a notifiable disease to the World Organisation for Animal Health (OIE), specific guidelines on the

treatment and follow-up, and on the safeguard of persons, need to be obtained from the relevant competent authority'

Use during pregnancy, lactation or lay

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.
Use of the product is not recommended 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.. The effect of the active substances with acetylcholine esterase activity (e.g. organophosphate compounds) may be increased. The specific properties of piperazine (neuromuscular paralysis of the parasites) can antagonise the effect of pyrantel (spastic paralysis of the parasites).

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.

Incompatibilities

Not applicable.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
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

15. OTHER INFORMATION

Carton box containing 1 PVC/PVDC aluminium blister of 2 tablets.
Carton box containing 1 PVC/PVDC aluminium blister of 10 tablets.
Carton box containing 2 PVC/PVDC aluminium blisters of 10 tablets, with a total of 20 tablets.

Carton box containing 5 PVC/PVDC aluminium blisters of 10 tablets, with a total of 50 tablets.
Carton box containing 10 PVC/PVDC aluminium blisters of 10 tablets, with a total of 100 tablets.
Carton box containing 30 PVC/PVDC aluminium blisters of 10 tablets, with a total of 300 tablets.

Not all pack sizes may be marketed.

Approved 08 November 2018