ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Veloxa Chewable Tablets for Dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Active substances

	mg/chewable tablet
Febantel	150.0
Pyrantel (as embonate)	50.0
Praziquantel	50.0

3. PHARMACEUTICAL FORM

Chewable tablet.

4. PACKAGE SIZE

2 tablets
4 tablets
104 tablets
8 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(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf-life of half tablets: 2 days.

11. SPECIAL STORAGE CONDITIONS

This medicinal product does not require any special storage conditions.
Keep the blister in the outer carton. Each time an unused half tablet is stored it should be returned to the open blister space and the blister inserted back into the outer carton.

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

Lavet Pharmaceuticals Ltd.
Batthyány u. 6.
2143 Kistarcsa
Hungary

16. MARKETING AUTHORISATION NUMBER(S)

Vm 32823/4010

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Veloxa Chewable Tablets for Dogs
Febantel, Pyrantel embonate, Praziquantel

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Lavet

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot> {number}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.
Αποκλειστικά για κτηνιατρική χρήση.
Kizárólag állatgyógyászati alkalmazásra.
Uso veterinário.
Á usage vétérinaire

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Veloxa Chewable Tablets for Dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Lavet Pharmaceuticals Ltd.
Batthyány u. 6.
2143 Kistarcsa
Hungary

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Veloxa Chewable Tablets for Dogs

Febantel, Pyrantel embonate, Praziquantel

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

Active substances	mg/chewable tablet
Febantel	150.0
Pyrantel	50.0
(corresponding to Pyrantel embonate	144.0)
Praziquantel	50.0

Brownish, oval, divisible chewable tablets.

4. INDICATION(S)

Anthelmintic for treatment of mixed infections by the following roundworms and tapeworms in dogs and puppies:

Ascarids:	*Toxocara canis, Toxascaris leonina* (adult and late immature forms).
Hookworms:	*Uncinaria stenocephala, Ancylostoma canium* (adults)
Whipworms:	*Trichuris vulpis* (adults)
Tapeworms:	*Echinococcus spp., Taenia spp., Dipylidium caninum* (adult and immature forms)

5. CONTRAINDICATIONS

Do not use in animals with a known hypersensitivity to any of the active substances or the excipients.

6. ADVERSE REACTIONS

In very rare cases (less than 1 animal in 10,000 animals, including isolated reports) transient, mild gastrointestinal signs (e.g. vomiting) may occur.
If you notice any serious effects or other 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

For oral administration only.

Dosage
1 chewable tablet per 10 kg bodyweight (15 mg febantel, 5 mg pyrantel (as embonate) and 5 mg praziquantel/kg body weight).

Body weight (kg)	*Number of chewable tablets*
2.5-5	½
>5-10	1
>10-15	1 ½
>15-20	2
>20-25	2 ½
>25-30	3

For dogs weighing more than 30 kg (i.e. >30 kg) the Forte strength should be used.

9. ADVICE ON CORRECT ADMINISTRATION

The chewable tablets can be given directly to the dog or disguised in food. No starvation is needed before or after treatment.
Due to a lipid-coating of praziquantel and added flavour, the chewable tablets are taken by most dogs voluntarily.

Duration of Treatment

Not for use in dogs weighing less than 2 kg.

A single dose shall be used. 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(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

This veterinary medicinal product does not require any special storage conditions. Keep out of the sight and reach of children. Do not use after the expiry date which is stated on the blister and outer carton after EXP. The expiry date refers to the last day of that month. Shelf-life of half tablets: 2 days. Keep the blister in the outer carton. Each time an unused half tablet is stored, it should be returned to the open blister space and the blister inserted back into the outer carton.

12. SPECIAL WARNING(S)

Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.
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.

Special precautions for use in animals:
Tapeworm infestation is unlikely in pups less than 6 weeks of age.
The tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of animals.
To minimise the risk of re-infestation and new infestation, excreta should be collected and properly disposed of for 24 hours following treatment

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In the interests of good hygiene, persons administering the chewable tablet directly to a dog or by adding it to the dog's food, should wash their hands afterwards.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Other precaution
Since it contains praziquantel, the product is effective against *Echinococcus spp.* which do not occur in all EU member states but are becoming more common in some.
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.

Pregnancy and lactation:
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.
The chewable tablets may be used during lactation.

Interaction with other medicinal products and other forms of interaction:
Do not use simultaneously with piperazine as the anthelmintic effects of pyrantel and piperazine may be antagonized.
Concurrent use with other cholinergic compounds can lead to toxicity.
Plasma concentrations of praziquantel may be decreased by concomitant administration with drugs that increase the activity of cytochrome P-450 enzymes (e.g. dexamethasone, phenobarbital).

Overdose (symptoms, emergency procedures, antidotes)
In safety studies, a single dose of 5 times the recommended dose or greater gave rise to occasional vomiting.

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

Any unused veterinary medicinal products or waste materials derived from such veterinary medicinal products 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 protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

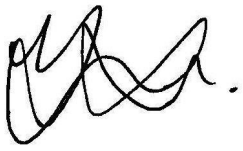
May 2020

15. OTHER INFORMATION

PVC/Aluminium/Polyamide blister-forming laminate with aluminium lidding foil containing 2 or 8 chewable tablets.

- Box containing 1 blister strip of 2 chewable tablets (2 chewable tablets)
- Box containing 2 blister strips of 2 chewable tablets (4 chewable tablets)
- Box containing 52 blister strips of 2 chewable tablets (104 chewable tablets)
- Box containing 1 blister strip of 8 chewable tablets (8 chewable tablets)
- Box containing 13 blister strips of 8 chewable tablets (104 chewable tablets)

Not all pack sizes may be marketed.
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.



Approved: 09 June 2020