

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE PACKAGE**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Veloxa Forte Chewable Tablets for Dogs  
(in Greece and Hungary)

Veloxa 525/504/175 mg Chewable Tablets for Dogs  
(in Finland, Norway and Sweden)

Veloxa XL Chewable Tablets for Dogs  
(in France, Ireland and United Kingdom)

Anthelmex Forte Chewable Tablets for Dogs  
(in Austria, Belgium, Germany, Luxembourg and The Netherlands)

Helm-Ex Chewable Tablets for Large Dogs  
(in Spain)

Xindex Forte Chewable Tablets for Dogs  
(in Italy)

Febantel, Pyrantel embonate, Praziquantel

**2. STATEMENT OF ACTIVE SUBSTANCES**

<b><u>Active substances</u></b>	<b><u>mg/chewable tablet</u></b>
Febantel	525.0
Pyrantel (as embonate)	175.0
Praziquantel	175.0

**3. PHARMACEUTICAL FORM**

Chewable tablet.

**4. PACKAGE SIZE**

2 tablets  
4 tablets  
8 tablets  
48 tablets  
96 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 32823/4011

**17. MANUFACTURER'S BATCH NUMBER**

Batch:{number}

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS**

*in Greece and Hungary*

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Veloxa Forte 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”**

Αποκλειστικά για κτηνιατρική χρήση.  
Kizárólag állatgyógyászati alkalmazásra.

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS**

*in Finland, Norway and Sweden*

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Veloxa 525/504/175 mg 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”**

Til dyr.  
Eläimille.  
För djur.

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS**

*in France, Ireland and United Kingdom*

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Veloxa XL 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.  
À usage vétérinaire.



**MINIMUM PARTICULARS TO APPEAR ON BLISTERS**

*in Austria, Belgium, Germany, Luxembourg and the Netherlands*

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Anthelmex Forte 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”**

Nur für Tiere.  
À usage vétérinaire.  
Uitsluitend voor diergeneeskundig gebruik.

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS**

*in Spain*

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Helm-Ex Chewable Tablets for large 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”**

Usó veterinario.

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS**

*in Italy*

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Xindex Forte 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”**

Solo per uso veterinario.

**B. PACKAGE LEAFLET**

**PACKAGE LEAFLET:**  
**Veloxa/ Veloxa 525/504/175 mg/Anthelmex/Xindex/Helm-Ex Chewable Tablets for Dogs**  
**Veloxa XL 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 Forte Chewable Tablets for Dogs  
*(in Greece and Hungary)*

Veloxa 525/504/175 mg Chewable Tablets for Dogs  
*(in Finland, Norway and Sweden)*

Veloxa XL Chewable Tablets for Dogs  
*(in France, Ireland and United Kingdom)*

Anthelmex Forte Chewable Tablets for Dogs  
*(in Austria, Belgium, Germany, Luxembourg and The Netherlands)*

Helm-Ex Chewable Tablets for Large Dogs  
*(in Spain)*

Xindex Forte Chewable Tablets for Dogs  
*(in Italy)*

Febantel, Pyrantel embonate, Praziquantel

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

<b><u>Active substances</u></b>	<b><u>mg/ chewable tablet</u></b>
Febantel	525.0
Pyrantel	175.0
(corresponding to Pyrantel embonate	504.0 mg)
Praziquantel	175.0
Brownish, oval, divisible chewable tablets.	

**4. INDICATION(S)**

Anthelmintic for treatment of mixed infections by the following roundworms and tapeworms in dogs over 17.5 kg:

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

Hookworms: *Uncinaria stenocephala*, *Ancylostoma caninum* (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 35 kg bodyweight (15 mg febantel, 5 mg pyrantel (as embonate) and 5 mg praziquantel/ kg body weight).

<u>Body weight (kg)</u>	<u>Number of chewable tablets</u>
17.5	1/2
>17.5-35	1
>35-52.5	1 ½
>52.5-70	2

Do not use for treatment of dogs weighing less than 17.5 kg (i.e. <17.5 kg).

## 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*

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

Chewable tablet for smaller dogs is recommended for use in dogs less than 17.5 kg bodyweight.

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.

Use during pregnancy or 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

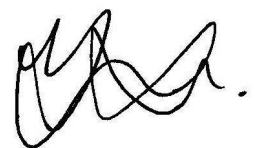
**15. OTHER INFORMATION**

PVC/Aluminium/Polyamide blister-forming laminate with aluminium lidding foil containing 2 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 4 blister strips of 2 chewable tablets (8 chewable tablets)
- Box containing 24 blister strips of 2 chewable tablets (48 chewable tablets)
- Box containing 48 blister strips of 2 chewable tablets (96 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