[Version 8.1,01/2017]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Veloxa 175/504/525 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)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:

Active substances:	mg
Febantel	525.0
Pyrantel	175.0
(corresponding to Pyrantel embonate)	504.0
Praziquantel	175.0

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Chewable tablet.
Brownish, oval, divisible tablet. It can be divided into equal parts.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

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. and Dipylidium caninum (adult and immature forms).

4.3 Contraindications

Do not use in animals with a known hypersensitivity to any of the active substances or the excipients.
Please see also sections 4.7 and 4.8.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

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.

4.6 Adverse reactions (frequency and seriousness)

In very rare cases (less than 1 animal in 10,000 animals, including isolated reports) transient, mild gastrointestinal signs (e.g. vomiting) may occur.

4.7 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. 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.

4.8 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).

4.9 Amounts to be administered and administration route

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).

Body weight (kg)	*Number of chewable tablets*
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).
To ensure administration of a correct dose, body weight should be determined as accurately as possible.

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

In safety studies, a single dose of 5 times the recommended dose or greater gave rise to occasional vomiting.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, febantel combinations.
ATC vet code: QP52AA51.

5.1 Pharmacodynamic properties

In this fixed combination product 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 all *Taenia spp, Dipylidium caninum, Echinococcus granulosus* and *Echinococcus multilocularis*.
Praziquantel acts against adult and immature forms of these parasites.
Praziquantel is very rapidly absorbed and distributed throughout the parasite. Both in vitro and in vivo studies have shown that praziquantel causes severe damage to the parasite integument, resulting in contraction and paralysis. There is an almost instantaneous tetanic contraction of the parasite

musculature and a rapid vacuolisation of the syncytial tegument. This rapid contraction has been explained by changes in divalent cation fluxes, especially calcium.

Pyrantel acts as a cholinergic agonist. Its mode of action is to stimulate nicotinic cholinergic receptors of the parasite, induce spastic paralysis and thereby allow removal from the gastro-intestinal (GI) system by peristalsis.

Within the mammalian system febantel undergoes ring closure forming fenbendazole and oxfendazole. It is these chemical entities which exert the anthelmintic effect by inhibition of tubulin polymerization. Formation of microtubules is thereby prevented, resulting in disruption to structures vital to the normal functioning of the helminth. Glucose uptake, in particular, is affected, leading to depletion in cell ATP. The parasite dies upon exhaustion of its energy reserves, which occurs 2-3 days later.

5.2 Pharmacokinetic particulars

After oral administration, praziquantel is almost completely absorbed from the intestinal tract. After absorption, the drug is widely distributed in the organism, metabolized into inactive forms in the liver and secreted in bile. It is excreted within 24 hours to more than 95% of the administered dosage.
The embonate salt of pyrantel has low aqueous solubility an attribute that reduces absorption from the gut and allows the drug to reach and be effective against parasites in the large intestine. Following absorption, pyrantel embonate is quickly and almost completely metabolised into inactive components which are rapidly excreted in the urine.
Febantel is an inactive pro-drug which is absorbed and then metabolised relative rapidly to a number of metabolites, including fenbendazole and oxfendazole, which have anthelmintic activity.
Following the single oral administration of this veterinary medicinal product the maximum plasma concentrations of praziquantel, pyrantel, fenbendazole and oxfendazole were found 327, 81, 128 and 165 ng/ml and were obtained after 2.2, 4.5, 5.2 and 6.3 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetyl palmitate
Starch, pregelatinised
Sodium starch glycolate (type A)
Colloidal anhydrous silica
Magnesium stearate
Artificial beef flavour

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf-life of half tablets: 2 days.

6.4. Special precautions for storage

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.

6.5 Nature and composition of immediate packaging

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.

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

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

Active substances	mg/chewable tablet
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.,
2143 Kistarcsa, Batthyány u. 6.

16. MARKETING AUTHORISATION NUMBER(S)

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.
Á 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"

Uso 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.
2143 Kistarcsa, Batthyány u. 6.
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)

Active substances	mg/ chewable tablet
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 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 35 kg bodyweight (15 mg febantel, 5 mg pyrantel (as embonate) and 5 mg praziquantel/ kg body weight).

Body weight (kg)	*Number of chewable tablets*
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

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.