SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Veloxa Chewable Tablets for Dogs
(in France, Greece, Hungary, Ireland, Portugal, and United Kingdom)

Veloxa vet 150/144/ 50 mg Chewable Tablets for Dogs
(in Finland and Sweden)

Veloxa 150/144/ 50 mg Chewable Tablets for Dogs
(in Denmark and Norway)

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

Helm-Ex Chewable Tablets for Dogs
(in Spain)

Xindex Chewable Tablets for Dogs
(in Italy)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:

Active substances	mg
Febantel	150.0
Pyrantel	50.0
(corresponding to Pyrantel embonate	144.0)
Praziquantel	50.0
Excipients	
For a full list of excipients, see section 6.1	

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

Broad-spectrum 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 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.
Tapeworm infestation is unlikely in pups less than 6 weeks of age.

4.5 Special precautions for use

i) Special precautions for use in animals

None.

ii) Special precautions to be taken by the person administering the 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.

4.6 Adverse reactions (frequency and seriousness)

In very rare cases 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 administra **SUMMARY OF PRODUCT CHARACTERISTICS**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

Veloxa 525/504/175 mg Chewable Tablets for Dogs
(in Denmark and Norway)

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 Forte Chewable Tablets for 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
Excipients	
For a full list of excipients, see section 6.1	

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

Broad-spectrum 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.
Tapeworm infestation is unlikely in pups less than 6 weeks of age.

4.5 Special precautions for use

i) Special precautions for use in animals

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

ii) Special precautions to be taken by the person administering the 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.

4.6 Adverse reactions (frequency and seriousness)

In very rare cases 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
For treatment of dogs 1 chewable tablet per 35 kg bodyweight orally (15 mg f ebantel, 5 mgpyrantel (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).

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

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.

4.11 Withdrawal period

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 Incompatibilities

Not applicable.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Chewable tablet halves should be used within 2 days.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.
Each time an unused half chewable tablet is stored it should be returned to the open blister space and inserted back into the folding box and kept in a safe place out of the reach of children.

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, if appropriate

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
1161 Budapest
Ottó u. 14
Hungary

8. MARKETING AUTHORISATION NUMBER

Vm: 32823/4010

9. DATE OF FIRST AUTHORISATION

Date: 16 January 2013

10. DATE OF LAST REVISION OF THE TEXT

Date: April 2014

PROHIBITION OF SALE, SUPPLY AND/OR USE
Not applicable.

1.B.2 LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

Veloxa 525/504/175 mg Chewable Tablets for Dogs
(in Denmark and Norway)

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 Forte Chewable Tablets for Dogs
(in Spain)

Xindex Forte Chewable Tablets for Dogs
(in Italy)

Febantel, Pyrantel embonate, Praziquantel

2. STATEMENT OF ACTIVE AND OTHER 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

1 blister strip of 2 chewable tablets
2 blister strips of 2 chewable tablets
4 blister strips of 2 chewable tablets
24 blister strips of 2 chewable tablets
48 blister strips of 2 chewable tablets

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

Read the package leaflet before use.

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}
Tablet halves should be used within 2 days.

11. SPECIAL STORAGE CONDITIONS

Unused half tablet should be returned to the open blister space and inserted back into the folding box.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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.

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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder:
Lavet Pharmaceuticals Ltd.,
1161 Budapest, Ottó u. 14., Hungary

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

in Greece, Hungary, and Portugal

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.
Uso veterinario.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

in Denmark and Norway

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.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

in Finland and Sweden

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Veloxa vet 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”

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 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"

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.

1.B.3 PRODUCT INFORMATION

PACKAGE LEAFLET

Veloxa Forte / Veloxa vet 525/504/175 mg / Veloxa 525/504/175 mg / Anthelmex Forte / Helm-Ex Forte / Xindex Forte / 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

Marketing authorisation holder:
Lavet Pharmaceuticals Ltd.,
1161 Budapest, Ottó u. 14., Hungary

Responsible for batch release:
Lavet Pharmaceuticals Ltd.,
Kistarcsa, 2143 Batthyány u. 6., Hungary

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

Veloxa 525/504/175 mg Chewable Tablets for Dogs
(in Denmark and Norway)

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 Forte Chewable Tablets for 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)

Broad-spectrum 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 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

For treatment of dogs 1 chewable tablet per 35 kg bodyweight orally (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

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

This medicinal product does not require any special storage conditions.

Keep out of the reach and sight of children. Do not use after the expire date which is stated on the blister and the outer carton after “EXP”.
Chewable tablets halves should be used within 2 days. Each time an unused half chewable tablet is stored it should be returned to the open blister space and inserted back into the folding box and kept in a safe place out of the reach of children.

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.
Tapeworm infestation is unlikely in pups less than 6 weeks of age.

Special precautions for use in animals

Do not exceed the stated dosage when treating pregnant bitches. Chewable tablet for smaller dogs is recommended for use in dogs less than 17.5 kg bodyweight.

User warnings

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.

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.

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).

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

For animal treatment only.

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.

tion route

For oral administration only.

Dosage
For treatment of dogs 1 chewable tablet per 10 kg bodyweight orally (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.

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

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.

4.11 Withdrawal period

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 Incompatibilities

Not applicable.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Chewable tablet halves should be used within 2 days.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.
Each time an unused half chewable tablet is stored it should be returned to the open blister space and inserted back into the folding box and kept in a safe place out of the reach of children.

6.5 Nature and composition of immediate packaging

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.

6.7 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

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
1161 Budapest
Ottó u. 14
Hungary

8. MARKETING AUTHORISATION NUMBER

Vm: 32823/4010

9. DATE OF FIRST AUTHORISATION

Date: 16 January 2013

10. DATE OF LAST REVISION OF THE TEXT

Date: April 2014

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.