SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Drontal Plus Flavour Tablets for Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Constituents	**mg per tablet**
Febantel	150.0
Pyrantel embonate	144.0
Praziquantel	50.0
Excipients	
Artificial beef flavour irradiated	116.5

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablet
A light brown to brown, round, flat tablet, cross scored on one side for oral administration to dogs.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

For the control of the following gastrointestinal tapeworms and roundworms 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., Dipylidium caninum* (adult and immature forms)

4.3 Contraindications

Do not use simultaneously with piperazine compounds.

4.4 Special warnings for each target species

As a precautionary measure to prevent the establishment of *Echinococcus multilocular*is in the UK and Ireland, it is recommended that all dogs and cats entering the country be treated with praziquantel.

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

i) Special precautions for use in animals

Any part used tablet should be discarded
Consult a veterinary surgeon before treating pregnant animals for roundworms.
Do not exceed the stated dose when treating pregnant bitches.

ii) Special precautions to be taken by the person administering the medicinal product to animals

In the interests of good hygiene, persons administering the tablet directly to the dog or by adding it to the dog's food, should wash their hands afterwards.

4.6 Adverse reactions (frequency and seriousness)

None known

4.7 Use during pregnancy, lactation or lay

Consult a veterinary surgeon before treating pregnant animals for roundworms.
The product may be used during lactation (see Section 4.9 below).

4.8 Interaction with other medicinal products and other forms of interaction

Do not use simultaneously with piperazine compounds.

4.9 Amount(s) to be administered and administration route

The recommended dose rates are: 15 mg/kg bodyweight febantel, 14.4 mg/kg pyrantel and 5 mg/kg praziquantel. This is equivalent to 1 tablet per 10 kg (22 lbs) bodyweight.

Puppies and Small Dogs:	
3-5 kg bodyweight	= ½ tablet
>5-10 kg bodyweight	1 tablet
Medium Dogs:	
>10-15 kg bodyweight	= 1 ½ tablets
>15-20 kg bodyweight	= 2 tablets
>20-25 kg bodyweight	= 2 ½ tablets
>25-30 kg bodyweight	= 3 tablets
Large Dogs:	
>30-35 kg bodyweight	= 3 ½ tablets
>35-40 kg bodyweight	= 4 tablets

For oral administration, the tablets can be given to the dog or disguised in food. No starvation is needed before, or after, treatment.

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 3 kg.

For the control of *Toxocara*, nursing bitches should be dosed 2 weeks after giving birth and every two weeks until weaning.

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.

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

The product is well tolerated in dogs. In safety studies doses of 5 x or greater gave rise to occasional vomiting.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

This product contains anthelmintics active against gastrointestinal roundworms and tapeworms. The product contains three active substances:

1. Febantel, a probenzimidazole,

2. Pyrantel embonate (pamoate) a tetrahydropyrimidine derivative,

3. Praziquantel, a partially hydrogenated pyrazinoisoquinoline derivative

ATC VetCode: QP52AF30

5.1 Pharmacodynamic properties

In this fixed combination 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 *Taenia spp*; *Dipylidium caninum; Echinococcus granulosus* and *Echinococcus multilocularis*. Praziquantel acts against all adult and immature forms of these parasites.

Praziquantel is very rapidly absorbed through the parasite's surface 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 the contraction and paralysis of the parasites. 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 of the nematodes 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 polymerisation. Formation of microtubules is thereby prevented, resulting in disruption of structures vital to the normal functioning of the helminth. Glucose uptake, in particular is affected, leading to a depletion in cell ATP. The parasite dies upon exhaustion of its energy reserves, which occurs 2-3 days later.

5.2 Pharmacokinetic particulars

No data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Artificial beef flavour irradiated
Maize starch
Lactose monohydrate
Microcrystalline cellulose
Povidone K25
Magnesium sterarate
Sodium laurilsulfate
Silica colloidal anhydrous

6.2 Incompatibilities

Not applicable.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years.

6.4 Special precautions for storage

Do not store above 25^{o}C.

6.5 Nature and composition of immediate packaging

Container:	Aluminium foil blister or polyethylene-coated aluminium blister
Container colour:	Silver or white coloured
Container sizes:	Cartons containing 2, 8, 24, and 104 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 product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Bayer plc
Animal Health Division
Bayer House
Strawberry Hill
Newbury
Berkshire
RG14 1JA

8. MARKETING AUTHORISATION NUMBER

Vm: 00010/4158

9. DATE OF FIRST AUTHORISATION

Date: 30 April 2008

10. DATE OF LAST REVISION OF THE TEXT

Date: February 2014

12 February 2014

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Drontal Plus Flavour Bone Shaped Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Constituents	mg/tablet
Febantel	150.0
Pyrantel embonate	144.0
Praziquantel	50.0
Relevant Constituents of the Excipients	
Artificial beef flavour Irradiated	116.5

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablet.
A pale brown to brown, bone shaped tablet scored on both sides for oral administration to dogs.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

For the control of 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 simultaneously with piperazine compounds
Do not exceed the stated dosage when treating pregnant bitches.

4.4 Special warnings for each target species

Fleas serve as intermediate hosts for one common type of tapeworm - *Dipylidium caninum*. Tapeworm infestation is certain to re-occur unless control of intermediate hosts such as fleas, mice etc. is undertaken.

4.5 Special precautions for use

i. Special precautions for use in animals

Any part-used tablets should be discarded.

ii. Special precautions to be taken by the person administering the medicinal product to animals

In the interests of good hygiene, persons administering the tablet directly to a dog or by adding it to the dog's food, should wash their hands afterwards.

iii. Other precautions

None.

4.6 Adverse reactions (frequency and seriousness)

None known

4.7 Use during pregnancy, lactation or lay

Consult a veterinary surgeon before treating pregnant animals for roundworms (see also Section 4.3 above).

The tablets may be used during lactation (see Section 4.8 below).

4.8 Interaction with other medicinal products and other forms of interaction

Piperazine (see Section 4.3 above).

4.9 Amount(s) to be administered and administration route

For oral administration only.

Dosage

The recommended dose rates are:15 mg/kg bodyweight febantel, 14.4 mg/kg pyrantel and 5 mg/kg praziquantel. This is equivalent to 1 tablet per 10 kg bodyweight

Puppies and Small Dogs:

3-5 kg bodyweight	= ½ tablet
6-10 kg bodyweight	1 tablet

Medium Dogs:

11-15 kg bodyweight	= 1 ½ tablets
16-20 kg bodyweight	= 2 tablets
21-25 kg bodyweight	= 2 ½ tablets
26-30 kg bodyweight	= 3 tablets

Large Dogs:

31-35 kg bodyweight	= 3 ½ tablets
36-40 kg bodyweight	= 4 tablets

Administration and Duration of Treatment

Oral administration, the tablet(s) can be given directly to the dog or disguised in food. Access to normal diet does not need to be limited before or after treatment.

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 3 kg.

For the control of *Toxocara*, nursing bitches should be dosed 2 weeks after giving birth and every 2 weeks until weaning.
For routine control adult dogs should be treated every 3 months. In the event of a heavy roundworm infestation, a repeat dose should be given after 14 days.

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

Benzimidazoles possess a wide safety margin. Pyrantel is not absorbed systemically to any extent. Praziquantel has a wide safety margin of up to five times the normal dose.

4.11 Withdrawal period(s)

Not applicable

5. PHARMACOLOGICAL PROPERTIES

The product contains anthelmintics active against roundworms and tapeworms. The product contains three active substances:

1) Febantel

2) Pyrantel embonate (pamoate)
and

3) Praziquantel, a partially hydrogenated pyrazino-isoquinoline derivative used widely as an anthelmintic for both human and veterinary use.

ATC Vet Code: QP52AC55

5.1 Pharmacodynamic properties

In this fixed combination product pyrantel and febantel act synergistically 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.*
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.

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 a depletion in cell ATP. The parasite dies upon exhaustion of its energy reserves, which occurs 2-3 days later.

5.2 Pharmacokinetic particulars

Praziquantel is very rapidly absorbed and distributed throughout the parasite. Both *in vivo and in* vitro 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.

Since it contains praziquantel, the product is effective against *Echinococcus multilocularis* which does not occur in the UK but is becoming more common in some European countries.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch
Lactose monohydrate
Microcrystalline cellulose
Povidone
Magnesium stearate
Sodium laurilsulfate

Colloidal anhydrous silica
Artificial beef flavour irrad.

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years

6.4 Special precautions for storage

Do not store above 25ºC.

6.5 Nature and composition of immediate packaging

Container material :	Polypropylene-coated aluminium foil
Container colour :	White.
Container sizes :	Cartons containing 2, 6, 24, 102 and 108 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

UK Only	IE Only
Bayer plc, Animal Health Division, Bayer House, Strawberry Hill, Newbury, Berkshire RG14 1JA	Bayer Ltd, Animal Health Division, The Atrium, Blackthorn Road, Dublin 18, Ireland

8. MARKETING AUTHORISATION NUMBER(S)

UK Only	IE Only
Vm 00010/4115	VPA 10021/14/4

9. DATE OF FIRST AUTHORISATION

UK Only	IE Only
08 June 2000	21 October 2005

10. DATE OF LAST REVISION OF THE TEXT

UK Only	IE Only
June 2011	TBC

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Drontal Plus Flavour Tablets for Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Constituents	**mg per tablet**
Febantel	150.0
Pyrantel embonate	144.0
Praziquantel	50.0
Excipients	
Artificial beef flavour irradiated	116.5

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablet
A light brown to brown, round, flat tablet, cross scored on one side for oral administration to dogs.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

For the control of the following gastrointestinal tapeworms and roundworms 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., Dipylidium caninum* (adult and immature forms)

4.3 Contraindications

Do not use simultaneously with piperazine compounds.

4.4 Special warnings for each target species

As a precautionary measure to prevent the establishment of *Echinococcus multilocular*is in the UK and Ireland, it is recommended that all dogs and cats entering the country be treated with praziquantel.

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

i) Special precautions for use in animals

Any part used tablet should be discarded
Consult a veterinary surgeon before treating pregnant animals for roundworms.
Do not exceed the stated dose when treating pregnant bitches.

ii) Special precautions to be taken by the person administering the medicinal product to animals

In the interests of good hygiene, persons administering the tablet directly to the dog or by adding it to the dog's food, should wash their hands afterwards.

4.6 Adverse reactions (frequency and seriousness)

None known

4.7 Use during pregnancy, lactation or lay

Consult a veterinary surgeon before treating pregnant animals for roundworms.
The product may be used during lactation (see Section 4.9 below).

4.8 Interaction with other medicinal products and other forms of interaction

Do not use simultaneously with piperazine compounds.

4.9 Amount(s) to be administered and administration route

The recommended dose rates are: 15 mg/kg bodyweight febantel, 14.4 mg/kg pyrantel and 5 mg/kg praziquantel. This is equivalent to 1 tablet per 10 kg (22 lbs) bodyweight.

Puppies and Small Dogs:	
3-5 kg bodyweight	= ½ tablet
>5-10 kg bodyweight	1 tablet
Medium Dogs:	
>10-15 kg bodyweight	= 1 ½ tablets
>15-20 kg bodyweight	= 2 tablets
>20-25 kg bodyweight	= 2 ½ tablets
>25-30 kg bodyweight	= 3 tablets
Large Dogs:	
>30-35 kg bodyweight	= 3 ½ tablets
>35-40 kg bodyweight	= 4 tablets

For oral administration, the tablets can be given to the dog or disguised in food. No starvation is needed before, or after, treatment.

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 3 kg.

For the control of *Toxocara*, nursing bitches should be dosed 2 weeks after giving birth and every two weeks until weaning.

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.

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

The product is well tolerated in dogs. In safety studies doses of 5 x or greater gave rise to occasional vomiting.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

This product contains anthelmintics active against gastrointestinal roundworms and tapeworms. The product contains three active substances:

4. Febantel, a probenzimidazole,

5. Pyrantel embonate (pamoate) a tetrahydropyrimidine derivative,

6. Praziquantel, a partially hydrogenated pyrazinoisoquinoline derivative

ATC VetCode: QP52AF30

5.1 Pharmacodynamic properties

In this fixed combination 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 *Taenia spp*; *Dipylidium caninum; Echinococcus granulosus* and *Echinococcus multilocularis*. Praziquantel acts against all adult and immature forms of these parasites.

Praziquantel is very rapidly absorbed through the parasite's surface 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 the contraction and paralysis of the parasites. 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 of the nematodes 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 polymerisation. Formation of microtubules is thereby prevented, resulting in disruption of structures vital to the normal functioning of the helminth. Glucose uptake, in particular is affected, leading to a depletion in cell ATP. The parasite dies upon exhaustion of its energy reserves, which occurs 2-3 days later.

5.2 Pharmacokinetic particulars

No data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Artificial beef flavour irradiated
Maize starch
Lactose monohydrate
Microcrystalline cellulose
Povidone K25
Magnesium sterarate
Sodium laurilsulfate
Silica colloidal anhydrous

6.2 Incompatibilities

Not applicable.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years.

6.4 Special precautions for storage

Do not store above 25^{o}C.

6.5 Nature and composition of immediate packaging

Container:	Aluminium foil blister or polyethylene-coated aluminium blister
Container colour:	Silver or white coloured
Container sizes:	Cartons containing 2, 8, 24, and 104 tablets Not all pack sizes may be marketed.

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

7. MARKETING AUTHORISATION HOLDER

Bayer plc
Animal Health Division
Bayer House
Strawberry Hill
Newbury
Berkshire
RG14 1JA

8. MARKETING AUTHORISATION NUMBER

Vm: 00010/4158

9. DATE OF FIRST AUTHORISATION

Date: 30 April 2008

10. DATE OF LAST REVISION OF THE TEXT

Date: February 2014

12 February 2014

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Drontal Plus XL Flavour Tablets for Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:	mg per tablet
Febantel	525.0
Pyrantel embonate	504.0
Praziquantel	175.0
Excipients	
Artificial beef flavour Irradiated	408.0

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablet.
Pale brown to brown oval shaped divisible tablet scored on both sides.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

For the control of the following roundworms and tapeworms in adult dogs:

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 simultaneously with piperazine compounds.

4.4 Special warnings for each target species

Fleas serve as intermediate hosts for one common type of tapeworm - *Dipylidium caninum*. Tapeworm infestation is certain to re-occur unless control of intermediate hosts such as fleas, mice etc. is undertaken.

Since it contains praziquantel, the product is effective against *Echinococcus multilocularis,* which does not occur in the UK or Ireland but is becoming more common in some European countries. As a precautionary measure to prevent establishment of *E multilocularis* in the UK and Ireland, it is recommended that all dogs entering the country be treated with praziquantel.

4.5 Special precautions for use

i) Special precautions for use in animals

Any part-used tablets should be discarded.
Do not exceed the stated dose when treating pregnant bitches.

ii) Special precautions to be taken by the person administering the medicinal product to animals

In case of accidental ingestion, seek medical advice and show package leaflet to the physician.

In the interests of good hygiene, persons administering the tablet directly to a dog or by adding it to the dog's food, should wash their hands afterwards.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy and lactation

Consult a veterinary surgeon before treating pregnant animals for roundworms.
Drontal Plus XL Flavour Tablets may be used during lactation (see Section 4.9 below).

4.8 Interaction with other medicinal products and other forms of interaction

Do not use simultaneously with piperazine.
Concurrent use with other cholinergic compounds is not recommended.

4.9 Amount(s) to be administered and administration route

Dosage

The recommended dose rates are: 15 mg/kg bodyweight febantel,
14.4 mg/kg pyrantel and 5 mg/kg praziquantel. This is equivalent to 1 tablet per 35 kg bodyweight as follows:

Dosages are as follows:

Body weight (kg)	Tablet quantity
17.5	½
>17.5 - 35	1

>35 - 52.5	1 ½
>52.5 - 70	2

Drontal Plus Flavour Tablets should be used to achieve accurate dosing in dogs weighing less than 17.5 kg. The dose is equivalent to 1 tablet per 10 kg.

Administration and Duration of Treatment

Oral administration: the tablet(s) can be given directly to the dog or disguised in food. No starvation is needed before or after treatment.

For routine treatment a single dose is recommended.

For the control of *Toxocara*, nursing bitches should be dosed 2 weeks after giving birth and every 2 weeks until weaning.

For routine control adult dogs should be treated every 3 months. In the event of a heavy roundworm infestation, a repeat dose should be given after 14 days.

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

Drontal Plus XL Flavour Tablets are well tolerated in dogs. In safety studies doses of 5 x or greater gave rise to occasional vomiting.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:
Anthelmintics, tetrahydropyrimidine

ATC VetCode: QP52AF30
The product contains anthelmintics active against roundworms and tapeworms. The product contains three active substances:

1) Febantel, a pro-benzimidazole.
2) Pyrantel embonate (pamoate), a tetrahydropyrimidine derivative, and
3) Praziquantel, a partially hydrogenated pyrazino-isoquinoline derivative.

5.1 Pharmacodynamic Properties

In this fixed combination product pyrantel and febantel act synergistically against 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.*

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 vivo and in* vitro 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 polymerisation. 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 a depletion in cell ATP. The parasite dies upon exhaustion of its energy reserves, which occurs 2-3 days later.

5.2 Pharmacokinetic Properties

No data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Artificial beef flavour Irradiated
Maize starch
Lactose monohydrate
Microcrystalline cellulose
Povidone K25
Magnesium stearate
Sodium laurilsulfate
Silica colloidal anhydrous

6.2 Incompatibilities

None known.

6.3 Shelf-life

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

6.4 Special precautions for storage

Do not store above 25ºC.
Any part used tablets should be discarded

6.5 Nature and composition of immediate packaging

Container material: PCTFE/PVC-aluminium foil strip

Container colour: White

Container sizes: Cartons containing 2, 8, 48 and 96 tablets
Not all pack sizes may be marketed.

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

7. MARKETING AUTHORISATION HOLDER

UK Only:	IE Only:
Bayer plc, Animal Health Division, Bayer House, Strawberry Hill, Newbury, Berkshire RG14 1JA	Bayer Ltd, Animal Health Division, The Atrium, Blackthorn Road, Dublin 18, Ireland

8. MARKETING AUTHORISATION NUMBERS

UK Only:	IE Only:
Vm 00010/4153	VPA 10021/55/1

9. DATE OF FIRST AUTHORISATION

UK Only:	IE Only:
31 March 2008	20 March 2009

10. DATE OF LAST REVISION OF THE TEXT

UK Only:	IE Only:
November 2013	TBC

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