PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Outer carton, pack sizes of 50ml and 100ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

[The applicable local name will be reflected with “Febantel 15 mg/ml / Pyrantel 5 mg/ml” below the name and “Oral Suspension” included when not already part of the local name.]

Member State	Local name
UK	Drontal Oral Suspension for Puppies

Febantel 15 mg/ml / Pyrantel 5 mg/ml
Oral Suspension [when not already part of the local name above]

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Febantel 15 mg/ml, pyrantel 5 mg/ml

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

50 ml
100 ml

5. TARGET SPECIES

For puppies and young dogs up to one year of age.

6. INDICATION(S)

For the treatment of roundworm infections in puppies and young dogs up to one year of age caused by:

Ascarids:	*Toxocara canis, Toxascaris leonina*
Hookworms:	*Ancylostoma caninum, Uncinaria stenocephala*
Whipworm:	*Trichuris vulpis*

[Indications should be included in countries where the product is available without prescription. Where the product is subject to prescription this text is not required but may be included to more easily determine the correct product.]

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Oral use

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the container: 12 weeks
Once opened, use by: … [second line to be included only when space permits]

11. SPECIAL STORAGE CONDITIONS

After opening, do not store above 25 ºC

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.
[Prescription status to be completed nationally]

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

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr. Alderton
Towcester
Northamptonshire
NN12 7LS

Manufactured by

- KVP Pharma + Veterinär Produkte GmbH, Projensdorfer Str. 324, 24106 Kiel Germany

- Vetoquinol BIOWET Sp. Z o.o., Żwirowa 140, 66-400 Gorzów Wlkp., Poland

16. MARKETING AUTHORISATION NUMBER

Vm 08007/3001

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle label, pack sizes of 50ml and 100ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

[The applicable local name will be reflected with "Febantel 15 mg/ml / Pyrantel 5 mg/ml" below the name and "Oral Suspension" included when not already part of the local name.]

Member State	Local name
UK	Drontal Oral Suspension for Puppies

Febantel 15 mg/ml / Pyrantel 5 mg/ml
Oral Suspension [when not already part of the local name above]

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

50 ml
100 ml

5. TARGET SPECIES

For puppies and young dogs up to one year of age.

6. INDICATION(S)

For the treatment of roundworm infections in puppies and young dogs caused by:
Ascarids: *Toxocara canis, Toxascaris leonina*
Hookworms: *Ancylostoma caninum, Uncinaria stenocephala*
Whipworm: *Trichuris vulpis*

[Indications should be included in countries where the product is available without prescription. Where the product is subject to prescription this text is not required but may be included to more easily determine the correct product.]

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Oral use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Once opened, use within 12 weeks.

11. SPECIAL STORAGE CONDITIONS

After opening, do not store above 25 ºC

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.
[Prescription status to be completed nationally]

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

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr. Alderton
Towcester
Northamptonshire
NN12 7LS

Manufactured by
- KVP Pharma + Veterinär Produkte GmbH, Projensdorfer Str. 324, 24106 Kiel, Germany
- Vetoquinol BIOWET Sp. Z o.o., Żwirowa 140, 66-400 Gorzów Wlkp., Poland

16. MARKETING AUTHORISATION NUMBER

Vm 08007/3001

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

PACKAGE LEAFLET

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

Marketing authorisation holder
Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr. Alderton
Towcester
Northamptonshire
NN12 7LS

Manufacturer responsible for batch release

- KVP Pharma und Veterinär Produkte GmbH, 24106 Kiel, Germany
- Vetoquinol BIOWET Sp. Z o.o., Żwirowa 140, 66-400 Gorzów Wlkp., Poland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

[The applicable local name will be reflected with “Febantel 15 mg/ml / Pyrantel 5 mg/ml” below the name and “Oral Suspension” included when not already part of the local name.]

Member State	Local name
UK	Drontal Oral Suspension for Puppies

Febantel 15 mg/ml / Pyrantel 5 mg/ml
Oral Suspension [when not already part of the local name above]

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

Each ml of the pale, red oral suspension contains

Active substances:

Febantel	15.0mg
Pyrantel	5.0mg (as pyrantel embonate 14.4mg)

Excipients:

Sodium benzoate (E211)	2.05mg
Sodium propionate (E281)	2.05mg
Ponceau 4R (E124)	0.25mg

4. INDICATION(S)

For the treatment of roundworm infections in puppies and young dogs up to one year of age caused by:

Ascarids:	*Toxocara canis*
	Toxascaris leonina
Hookworms:	*Ancylostoma caninum*
	Uncinaria stenocephala
Whipworm:	*Trichuris vulpis*

5. CONTRAINDICATIONS

Do not use in pregnant and lactating bitches.

Do not use simultaneously with compounds containing piperazine.

6. ADVERSE REACTIONS

In very rare cases mild transient digestive tract signs (e.g., vomiting diarrhoea) may occur.
The frequency of adverse reactions is defined using the following convention:

- Very rare (less than 1 animal in 10,000 animals, including isolated reports)

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon

7. TARGET SPECIES

Dogs (puppies and young dogs up to one year of age)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage and Treatment Schedule

For a single oral administration15 mg/kg bodyweight febantel and 5 mg/kg bodyweight pyrantel (as embonate) corresponding to 14.4 mg/kg pyrantel embonate, equivalent to 1 ml/kg bodyweight.

Through intrauterine and transmammary infection, ascarid infestation may occur in dogs at a very early age. For some animals, especially in case of severe infections, elimination of ascarids may be incomplete, and a potential risk of infections to humans can not be excluded. Where epidemiologically appropriate, it is recommended that treatment should be started at 2 weeks of age and should be performed repeatedly at suitable intervals (for example every two weeks) until weaning. Otherwise treatment should be based upon confirmed infection, for example the results of faecal examinations.

9. ADVICE ON CORRECT ADMINISTRATION

The product may be given directly to the animal or mixed with food. There are no dietary precautions to be taken. Mix the product by inversion of the container before drawing the required dose.

10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of reach and sight of children.
This unopened veterinary medicinal product does not require any special storage conditions. After opening, store the product at a temperature not exceeding 25 ºC.
Do not use this veterinary medicinal product after the expiry date stated on the label and carton after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening the container: 12 weeks

12. SPECIAL WARNING(S)

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

The safety of the product has not been assessed in puppies younger than 2 weeks and weighing less than 0.600 kg.

Do not use in pregnant and lactating bitches.

The anthelmintic effects of both pyrantel (spastic paralysis) and piperazine (neuromuscular paralysis) may be antagonised when the two drugs are used together.

Doses of up to 5 times the therapeutic level of the product have been administered to puppies and young dogs without clinical signs of intolerance arising.

At 10 times the recommended dose the first sign of intolerance – vomiting – was evident.

User warnings:

Wash hands after use.

Avoid direct contact with the skin and eyes. In case of accidental spillage wash the affected area immediately with clean running water.

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

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

14. . PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

15. OTHER INFORMATION

Pack sizes: 50 ml, 100 ml with 5ml syringe
(Not all pack sizes may be marketed)

Gavin Hall
Approved: 20 July 2024