LABELLING AND PACKAGE LEAFLET

A. LABELLING

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

{CARTON FOR PACK SIZES OF 2,4 TABLETS}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Beaphar WORMclear tablets for dogs

Praziquantel, Febantel, Pyrantel

2. STATEMENT OF ACTIVE SUBSTANCES

Each pork flavoured tablet contains 50 mg Praziquantel, 50 mg Pyrantel (equivalent to 144 mg pyrantel embonate) and 150 mg Febantel.

3. PHARMACEUTICAL FORM

Tablet.

4. PACKAGE SIZE

2,4 tablets.

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

In dogs: Treatment of mixed infections with gastrointestinal worms (roundworms & tapeworms). Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Directions:

Single dose: For oral administration.

1 tablet per 10 kg bodyweight.

To ensure administration of a correct dose, body weight should be determined as accurately as possible. It is important to follow the treatment recommendations presented below. Do not deviate from these recommendations without the advice of your veterinary surgeon.

Read the package leaflet before use.

Body weight (kg)	Tablets
GREATER THAN 3.0 up to 5.0 kg	½
GREATER THAN5.1 UP TO 10.0KG	1
GREATER THAN 10.1 UP TO 15.0KG	1½
GREATER THAN 15.1 UP TO 20.0KG	2

Tablets should be given directly by mouth or if necessary given with food. This medicine does not need to be given on an empty stomach.

Tablets can be divided in two or four equal doses.

Not for use in animals weighing less than 3 kg or less than 2 weeks of age.

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. 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 case of suspected heavy roundworm infestation, please contact your veterinary surgeon for diagnosis and treatment recommendation.

8. WITHDRAWAL PERIOD

N/A

9. SPECIAL WARNING(S), IF NECESSARY

User Warnings
In case of accidental ingestion, seek medical advice and show the package leaflet or carton to the physician. In the interests of good hygiene, persons administering the tablets directly to a dog or adding them to the dog's food should wash their hands afterwards.

If your dog receives other veterinary medicinal products, check with a veterinary surgeon or pharmacist before using this product.
Do not use simultaneously with other deworming products without veterinary advice.
Do not use in animals with a known allergy to the active ingredients or to any of the excipients.
Do not use in pregnant dogs, except under the advice of a veterinary surgeon.
If signs of disease persist or appear consult a veterinary surgeon.
Do not exceed the stated dose; in the event of an overdose seek immediate veterinary advice.
Dogs will continue to be reinfected with tapeworms unless the route of infection is controlled e.g. control of intermediate hosts such as fleas and mice.

10. EXPIRY DATE

EXP {month/year}
Do not use after the expiry date.

11. SPECIAL STORAGE CONDITIONS

Keep immediate packaging in outer carton. Discard any unused half tablets immediately.
Do not remove tablets from the blister until ready to use.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Please refer to package leaflet for disposal advice.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

AVM-GSL

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

C&H Generics Ltd
c/o Michael McEvoy and Co
Seville House
New Dock Street
Galway
Ireland

Distributor:
Beaphar UK Ltd
Rook Tree Farm
Withersfield Road
Great Wratting
Suffolk, CB9 7HD

16. MARKETING AUTHORISATION NUMBER

Vm 40162/4016

17. MANUFACTURER'S BATCH NUMBER

BN{number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{BLISTER FOIL TEXT}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Beaphar WORMclear tablets for dogs

Praziquantel, Febantel, Pyrantel.

2. NAME OF THE MARKETING AUTHORISATION HOLDER

C&H Generics Ltd

3. BATCH NUMBER

BN {number}

4. EXPIRY DATE

EXP {month/year}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For Animal Treatment Only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Beaphar WORMclear tablets for dogs

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

Marketing authorisation holder:	Manufacturer responsible for batch release:
C&H Generics Ltd, c/o Michael McEvoy and Co Seville House New Dock Street Galway Ireland	Chanelle Pharmaceutical Manufacturing Limited Loughrea Co. Galway Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Beaphar WORMclear tablets for dogs

Praziquantel, Febantel, Pyrantel

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

Beaphar WORMclear tablets for dogs are pale yellow pork-flavoured tablets with a cross breakline on one side. Each tablet contains 50 mg Praziquantel, 50 mg Pyrantel (equivalent to 144 mg Pyrantel Embonate) and Febantel 150 mg. The tablets can be divided into halves or quarters.

4. INDICATION(S)

In dogs: Treatment of mixed infections with gastrointestinal worms (roundworms & tapeworms) of the following species:

Roundworms (nematodes):
Ascarids: *Toxocara canis*, *Toxascaris leonina* (adult and late immature forms).
Hookworms: *Uncinaria stenocephala*, *Ancylostoma caninum* (adults).
Whipworms: *Trichuris vulpis* (adults).

Tapeworms (cestodes):
Tapeworms: *Echinococcus* species *(E. granulosus, E. multilocularis), Taenia* species *(T. hydatigena, T. pisiformis, T. taeniformis), Dipylidium caninum* (adult and immature forms).

5. CONTRAINDICATIONS

Do not use simultaneously with piperazine compounds as the anthelmintic effects of pyrantel and piperazine may be antagonized.
Do not use simultaneously with other deworming products without veterinary advice.
Do not use in animals with a known sensitivity to the active ingredients or to any of the excipients.

6. ADVERSE REACTIONS

In very rare cases slight and transient digestive tract disorders such as vomiting and /or diarrhoea may occur. In individual cases these signs can be accompanied by nonspecific signs such as lethargy, anorexia or hyperactivity.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports)

7. TARGET SPECIES

Dogs

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

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

The tablets can be given directly to the dog or disguised in food. No starvation is needed before, or after, treatment. The tablet can be divided in two or four equal doses.

It is important to follow the treatment recommendations presented below. Do not deviate from these recommendations without the advice of your veterinary surgeon.

Puppies and Small Dogs:

3 kg up to 5 kg bodyweight	½ tablet
Greater than 5 up to 10 kg bodyweight	1 tablet

Medium Dogs:

Greater than 10 up to 15 kg bodyweight	1 ½ tablets
Greater than 15 up to 20 kg bodyweight	2 tablets
Greater than 20 up to 25 kg bodyweight	2 ½ tablets
Greater than 25 up to 30 kg bodyweight	3 tablets

Large Dogs:

Greater than 30 up to 35 kg bodyweight	3 ½ tablets
Greater than 35 up to 40 kg bodyweight	4 tablets

Not for use in dogs weighing less than 3 kg.
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.

The product may be used in lactating bitches from two weeks after giving birth. It is advisable to treat the bitch at the same time as the puppies. 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 case of suspected heavy roundworm infestation, please contact your veterinary surgeon for diagnosis and treatment recommendations.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure administration of a correct dose, body weight should be determined as accurately as possible

10. WITHDRAWAL PERIOD

N/A

11. SPECIAL STORAGE PRECAUTIONS

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
This veterinary medicinal product does not require any special temperature storage conditions
Keep out of the sight and reach of children.
Discard any unused half tablets immediately.
Do not remove tablets from immediate packaging until required for use.
Keep immediate packaging in outer carton.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Do not use simultaneously with piperazine compounds as the anthelmintic effects of pyrantel and piperazine may be antagonized.
Concurrent use with other cholinergic compounds (e.g.neostigmine, propoxur and bethanechol) can lead to toxicity.
If your dog receives other veterinary medicinal products, check with a veterinary surgeon or pharmacist before using this product.

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.
Tapeworm infestation is unlikely in pups less than 6 weeks of age.
Development of parasite resistance to anthelmintics of a certain class can occur after frequent and repeated use of an anthelmintic from that class.
If signs of disease persist or appear consult a veterinary surgeon.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental ingestion, seek medical advice and show the package leaflet to the physician. In the interests of good hygiene, persons administering the tablets directly to a dog or adding them to the dog's food should wash their hands afterwards.

Other precautions:
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.

Pregnancy:
Do not exceed the stated dose, especially when treating pregnant bitches. In the event of an overdose seek immediate veterinary advice.

Consult a veterinary surgeon before treating pregnant animals.
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, especially when treating pregnant bitches.

Overdose (symptoms, emergency procedures, antidotes):
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.

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

Medicines should not be disposed of via wastewater. The product should not enter water courses as this may be dangerous for fish and other aquatic organisms. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

March 2020

15. OTHER INFORMATION

2, 4 tablets.
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For Animal Treatment Only

Distributor:

Beaphar UK Ltd
Withersfield Road
Great Wratting
Suffolk, CB9 7HD

Approved 16 March 2020