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

Manufacturer responsible for batch release:
Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway,
Ireland

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Beaphar WORMclear® tablets for dogs.

## 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

**Nematodes:**
**Ascarids:** *Toxocara canis, Toxascaris leonina* (adult and late immature forms).
**Hookworms:** *Uncinaria stenocephala, Ancylostoma caninum* (adults).
**Whipworms:** *Trichuris vulpis* (adults).
**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 in animals with a known sensitivity to the active ingredients or to any of the excipients.
Do not use simultaneously with other deworming products without veterinary advice.

## 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 body weight 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) body weight.
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 as presented here. Do not deviate from the recommendations without the advice of your veterinary surgeon.

| | Body weight (kg) | Tablets |
|---|---|---|
| Puppies and Small Dogs | Greater than 3.0 up to 5.0 kg | ½ |
| | Greater than 5.0 up to 10.0 kg | 1 |
| Medium Dogs | Greater than 10.0 up to 15.0 kg | 1½ |
| | Greater than 15.0 up to 20.0 kg | 2 |
| | Greater than 20.0 up to 25.0 kg | 2½ |
| | Greater than 25.0 up to 30.0 kg | 3 |
| Large Dogs | Greater than 30.0 up to 35.0 kg | 3½ |
| | Greater than 35.0 up to 40.0 kg | 4 |

Not for use in dogs weighing less than 3kg. 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. Do not remove tablets from immediate packaging until required for use. Keep immediate packaging in outer carton.
Discard any unused half tablets immediately.

**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.

For Animal Treatment Only.

**Overdose:**
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**
There are two pack sizes: 2 tablets per pack or 4 tablets per pack.

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

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