

VIRBANTEL- pyrantel pamoate/praziquantel tablet, chewable
Virbac AH, Inc

Virbantel
(pyrantel pamoate/praziquantel)
Flavored Chewables

Virbantel® Flavored Chewables

Package contents: bottle of 50 flavored chewables

Drug Facts

Active Ingredients (in each chewable): pyrantel pamoate (114 mg) and praziquantel (114 mg)

Purpose: De-wormer for Medium and Large Dogs Only (Greater than 25 pounds)

Uses: For the treatment and control of:

- Roundworms (*Toxocara canis*, *Toxascaris leonina*)
- Hookworms (*Ancylostoma caninum*, *Ancylostoma braziliense*, and *Uncinaria stenocephala*)
- Tapeworms (*Dipylidium caninum*, *Taenia pisiformis*)

When Using This Product:

- Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.
- Do not de-worm a dog or puppy that is sick. Consult a veterinarian for diagnosis of the illness.
- **Virbantel** Flavored Chewables are safe for use in puppies 12 weeks or older and adult dogs. Safety in breeding dogs and pregnant bitches has not been tested.

You May Notice:

Vomiting, loose stools (with or without blood) and decreased activity following treatment. If you notice these signs, contact a veterinarian.

Human Warning: Keep this and all medication out of the reach of children. To obtain product information, including a Safety Data Sheet (SDS), call 1-800-338-3659.

Directions

Directions: Each flavored chewable contains 114 mg of pyrantel pamoate and 114 mg of praziquantel. The dose for each drug is 2.27 mg per pound of body weight (5 mg/kg). Please refer to the following dosing table for help finding the right dose for your dog.

Virbantel Flavored Chewables Dosing Table

Dog Weight

6.0 to 25 pounds
25.1 to 50 pounds
50.1 to 100 pounds
100.1 to 150 pounds
150.1 to 200 pounds

Number of Chewables

Use the 30mg size.
1
2
3
4

- You should weigh your dog to make sure you are giving the right dose.
- Virbanel Flavored Chewables are palatable if offered by hand. If your dog does not voluntarily eat the chewable, you can hide the chewable in a small amount of food or place it in the back of the dog's mouth for forced swallowing.
- Make sure that the dog eats the complete dose.
- Watch your dog for a few minutes after dosing to make sure the chewable is not rejected.

Other Information:**Recommended De-Worming Schedule:**

Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. De-worming schedules may vary depending on the climate where you live and the activity of your dog.

Re-treatment: Re-treatment of your dog may be necessary as determined by laboratory fecal examination and/or if your dog is living where re-infections are likely to occur. Consult your veterinarian for assistance in the diagnosis and prevention of re-infection. In case of re-infection with tapeworms (*Dipylidium caninum*), consult your veterinarian for advice on how to remove fleas from the dog and the environment.

Manufactured by:

Virbac AH, Inc.
Fort Worth, TX 76137

Storage:

Store at controlled room temperature of 59-86°F (15-30°C).

Questions? Comments?

To report a suspected adverse reaction, call
1-800-338-3659.

2/2019 301799-03

Approved by FDA under NADA # 141-261

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VIRBANTEL

pyrantel pamoate/praziquantel tablet, chewable

Product Information

| | | | |
|--------------------------------|-----------------|---------------------------|---------------|
| Product Type | OTC ANIMAL DRUG | Item Code (Source) | NDC:51311-741 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------|
| PYRANTEL PAMOATE (UNII: 81BK194Z5M) (PYRANTEL - UNII:4QIH0N49E7) | PYRANTEL | 114 mg |
| PRAZIQUANTEL (UNII: 6490C9U457) (PRAZIQUANTEL - UNII:6490C9U457) | PRAZIQUANTEL | 114 mg |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|----------|
| Color | brown | Score | 2 pieces |
| Shape | ROUND | Size | 14mm |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:51311-741-10 | 1 in 1 BOX | | |
| 1 | | 50 in 1 BOTTLE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| NADA | NADA141261 | 09/03/2007 | |

Labeler - Virbac AH, Inc (131568396)

Registrant - Virbac AH, Inc (131568396)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------|---------|-----------|---------------------|
| Virbac Corporation | | 829166276 | manufacture |

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------------------|---------|-----------|---------------------|
| Legacy Pharmaceutical Packaging | | 143213275 | pack |

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------|---------|-----------|---------------------|
| Eurofins SF Analytical LLC | | 118214040 | analysis |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------|---------|-----------|---------------------|
| Cosma S.p.A | | 428655732 | api manufacture |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------|---------|-----------|---------------------|
| Megafine Pharma | | 925627080 | api manufacture |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------|---------|-----------|---------------------|
| Cipla | | 916940208 | api manufacture |

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|---------------------|
| SEQUENT RESEARCH LIMITED | | 676159446 | analysis |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------------|---------|-----------|---------------------|
| Alivira Animal Health Limited | | 650916617 | api manufacture |