

## **LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>**

**{CARTON FOR PACK SIZES OF 2, 4, 6 AND 8 TABLETS}**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

VetWorm Plus Tablets For Dogs.

**2. STATEMENT OF ACTIVE AND OTHER 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**

Tablets

**4. PACKAGE SIZE**

2, 4, 6, 8 tablets.

**5. TARGET SPECIES**

Dogs.

**6. INDICATION(S)**

In dogs: Treatment of mixed infections by some species of nematodes and cestodes.

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Read the package leaflet before use.

For oral administration.

1 tablet per 10 kg bodyweight.

**8. WITHDRAWAL PERIOD**

N/A

**9. SPECIAL WARNING(S), IF NECESSARY**

Do not use simultaneously with piperazine compounds as the anthelmintic effects of pyrantel and piperazine may be antagonized.

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.

Do not use in animals with a known sensitivity to the active ingredients or to any of the excipients.

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 when treating pregnant bitches.

#### **10. EXPIRY DATE**

EXP {month/year}

Discard any unused divided tablets.

#### **11. SPECIAL STORAGE CONDITIONS**

Do not use after expiry date.

This veterinary medicinal product does not require any special storage conditions

#### **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.

#### **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**

Chanelle Animal Health Ltd.  
7 Rodney Street  
Liverpool  
L1 9HZ  
U.K.

#### **16. MARKETING AUTHORISATION NUMBER**

Vm 11990/4062

#### **17. MANUFACTURER’S BATCH NUMBER**

BN{number}

**<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>**

**{CARTON FOR PACK SIZES OF 10 TABLETS, AND UPWARDS}**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

VetWorm Plus Tablets For Dogs.

**2. STATEMENT OF ACTIVE AND OTHER 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**

Tablets

**4. PACKAGE SIZE**

10, 12, 14, 16, 18, 20, 24, 28, 30, 32, 36, 40, 42, 44, 48, 50, 52, 56, 60, 70, 80, 84,  
90, 98, 100, 104, 106, 120, 140, 150, 180, 200, 204, 206, 250, 280, 300, 500 and  
1000 tablets.

**5. TARGET SPECIES**

Dogs.

**6. INDICATION(S)**

In dogs: Treatment of mixed infections by nematodes and cestodes 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).

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

For oral administration.

Read the package leaflet before use.

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

1 tablet per 10kg (22lbs) bodyweight. The tablets can be given directly to the dog or disguised in food. No starvation is needed before, or after, treatment.

Dosage table:

| <b>Bodyweight (kg)</b> | <b>Tablets</b>     |
|------------------------|--------------------|
| >0.5 – 2.5             | 1/4                |
| >2.5 – 5               | 1/2                |
| >5 - 10                | 1                  |
| >10 - 15               | 1½                 |
| >15 - 20               | 2                  |
| >20 - 25               | 2½                 |
| >25-30                 | 3                  |
| >30 - 35               | 3½                 |
| >35 - 40               | 4                  |
| >40                    | 1 tablet per 10 kg |

If there is a risk for re-infestation, the advice of a veterinarian should be sought regarding the need for and the frequency of repeat administration.

#### **8. WITHDRAWAL PERIOD**

N/A

#### **9. SPECIAL WARNING(S), IF NECESSARY**

Do not use simultaneously with piperazine compounds as the anthelmintic effects of pyrantel and piperazine may be antagonized.

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.

Do not use in animals with a known sensitivity to the active ingredients or to any of the excipients.

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 when treating pregnant bitches.

Refer to the package leaflet for additional warnings.

#### **10. EXPIRY DATE**

EXP {month/year}

Discard any unused divided tablets.

#### **11. SPECIAL STORAGE CONDITIONS**

Do not use after expiry date.

This veterinary medicinal product does not require any special storage conditions

**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.

**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**

Chanelle Animal Health Ltd.  
7 Rodney Street  
Liverpool  
L1 9HZ  
U.K.

**16. MARKETING AUTHORISATION NUMBER**

Vm 11990/4062

**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**

VetWorm Plus Tablets For Dogs.

Praziquantel, Febantel, Pyrantel.

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

Chanelle Animal Health 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**  
**VetWorm Plus Tablets for dogs**

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

Chanelle Animal Health Ltd.  
7 Rodney Street  
Liverpool  
L1 9HZ  
U.K.

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

VetWorm Plus Tablets For Dogs.

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

Each pork flavored tablet contains:

50 mg Praziquantel, 50 mg Pyrantel (equivalent to 144 mg pyrantel embonate) and 150 mg Febantel.

Pale yellow tablet with a cross breakline on one side.

The tablets can be divided into halves or quarters.

**4. INDICATION(S)**

In dogs: Treatment of mixed infections by nematodes and cestodes 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.

**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.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reactions 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).

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

## 7. TARGET SPECIES

Dogs

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

### 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.

1 VetWorm Plus 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.

Dosage table:

| Bodyweight (kg) | Tablets            |
|-----------------|--------------------|
| >0.5 – 2.5      | 1/4                |
| >2.5 - 5        | 1/2                |
| >5 - 10         | 1                  |
| >10 - 15        | 1½                 |
| >15 - 20        | 2                  |
| >20 - 25        | 2½                 |
| >25 - 30        | 3                  |
| >30 - 35        | 3½                 |
| >35 - 40        | 4                  |
| >40             | 1 tablet per 10 kg |

If there is a risk for re-infestation, the advice of a veterinarian should be sought regarding the need for and the frequency of repeat administration.

## 9. ADVICE ON CORRECT ADMINISTRATION

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

Discard any unused divided tablets.

## 10. WITHDRAWAL PERIOD

N/A

## 11. SPECIAL STORAGE PRECAUTIONS

Do not use after expiry date stated on the label.

This veterinary medicinal product does not require any special storage conditions.  
Keep out of the sight and reach of children.

## 12. SPECIAL WARNING(S)

Do not use simultaneously with piperazine compounds as the anthelmintic effects of pyrantel and piperazine may be antagonized.

Concurrent use with other cholinergic compounds can lead to toxicity.

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.

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 when treating pregnant bitches.

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

### User Precautions:

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.

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 humans, need to be obtained from the relevant competent authority.

For animal treatment only.

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

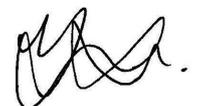
Dispose of empty packaging and any remaining product in the household refuse

## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

## 15. OTHER INFORMATION

2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 24, 28, 30, 32, 36, 40, 42, 44, 48, 50, 52, 56, 60, 70, 80, 84, 90, 98, 100, 104, 106, 120, 140, 150, 180, 200, 204, 206, 250, 280, 300, 500 and 1000 tablets.

Not all pack sizes may be marketed.



Approved: 18 February 2020