

<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

EziWormer 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 gastrointestinal roundworms. Tapeworms, hookworms and whipworms.

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 piperazine may block the action of pyrantel embonate contained in EziWormer Plus Tablets for Dogs.

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. Consult a veterinary surgeon before treating pregnant animals. 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.

Please 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

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

16. MARKETING AUTHORISATION NUMBER

Vm 40162/4000

17. MANUFACTURER’S BATCH NUMBER

BN{number}

AVM-GSL

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EziWormer 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 of roundworms, tapeworms, hookworms and whipworms of the following species

Ascarids: *Toxocara canis*, *Toxascaris leonina* (adult and late immature forms).

Hookworms: *Uncinaria stenocephala*, *Ancylostoma caninum* (adults).

Whipworms: *Trichuris vulpis* (adults).

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

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:

	Bodyweight (kg)	Tablets
Puppies and small dogs	3-5	½
	6-10	1
Medium dogs	11-15	1½
	16-20	2
	21-25	2½
	26-30	3
Large dogs	31-35	3½
	36-40	4
	>40	1 tablet per 10 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. It is advisable to

treat the bitch at the same time as the puppies. Not for use in dogs weighing less than 3 kg.

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

Do not use simultaneously with piperazine compounds as piperazine may block the action of pyrantel embonate contained in EziWormer Plus Tablets for Dogs. Other worming products may contain piperazine.

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. Consult a veterinary surgeon before treating pregnant animals. 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

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

16. MARKETING AUTHORISATION NUMBER

Vm 40162/4000

17. MANUFACTURER'S BATCH NUMBER

BN{number}

AVM-GSL

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{BLISTER FOIL TEXT}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EziWormer Plus 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.

PACKAGE LEAFLET
EziWormer 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

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

EziWormer Plus Tablets For Dogs.

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

Each pork flavoured 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 of roundworms, tapeworms, hookworms and whipworms of the following species

Ascarids: *Toxocara canis*, *Toxascaris leonina* (adult and late immature forms).

Hookworms: *Uncinaria stenocephala*, *Ancylostoma caninum* (adults).

Whipworms: *Trichuris vulpis* (adults).

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 piperazine may block the action of pyrantel embonate in EziWormer Plus Tablets for Dogs.

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 treated displaying adverse reaction(s))
- Common (more than 1 but less than 10 animals in 100 animals treated)
- Uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- Rare (more than 1 but less than 10 animals in 10,000 animals treated)
- Very rare (less than 1 animal in 10,000 animals treated, 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 tablet per 10 kg (22 lbs) bodyweight.

Dosage table:

	Bodyweight (kg)	Tablets
Puppies and small dogs	3-5	½
	6-10	1
Medium dogs	11-15	1½
	16-20	2
	21-25	2½
	26-30	3
Large dogs	31-35	3½
	36-40	4
	>40	1 tablet per 10 kg

For oral administration, the tablets can be given to the dog or disguised in food. No starvation is needed before, or after, treatment.

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

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.

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 piperazine may block the action of pyrantel embonate contained in EziWormer Plus Tablets for Dogs. Other worming products may contain piperazine.

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. Consult a veterinary surgeon before treating pregnant animals. 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

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

Medicines should not be disposed of via wastewater.

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

December 2016

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.

AVM-GSL

Approved: 17 August 2018

