<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

{CARTON FOR PACK SIZES OF 2TABLETS}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rofectan Plus Tablets For Dogs.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

50 mg/tablet Praziquantel, 144 mg/tablet Pyrantel Embonate (equivalent to 50 mg pyrantel) and 150 mg/tablet Febantel.

3. PHARMACEUTICAL FORM

Tablets.

4. PACKAGE SIZE

2tablets.

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

Treatment of gastrointestinal roundworms, tapeworms, hookworms and whipworms.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Single dose: For oral administration.

1 tablet per 10 kg bodyweight.

The tablet can be divided in two or four equal doses.

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 Rofectan Plus Tablets for Dogs.

Other worming products may contain piperazine.

Not for use in dogs weighing less than 3 kg.

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.

User Warnings

In case of accidental ingestion, seek medical advice and show the package leaflet or carton to the physician. Wash hands after use.

10. EXPIRY DATE

EXP {month/year}

Discard any unused divided tablets immediately.

11. SPECIAL STORAGE CONDITIONS

Do not use after expiry date.
This veterinary medicinal product does not require any special temperature storage conditions
Do not remove tablets from strip packaging until required for use.
Keep blister in outer carton.

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 REACH AND SIGHT OF CHILDREN"

Keep out of the site 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 40162/4013

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

Rofectan Plus Tablets For Dogs.

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

Rofectan 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

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rofectan Plus Tablets For Dogs.

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

Rofectan Plus Tablets For Dogs are pale yellow tablets with a cross breakline on one side. Each tablet contains 50 mg Praziquantel, 144mg Pyrantel Embonate (equivalent to 50 pyrantel) and 150 mg Febantel. The tablets can be divided into halves or quarters.

4. INDICATION(S)

In dogs and puppies: Treatment of gastrointestinal 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 Rofectan Plus Tablets For Dogs.
Other products may contain piperazine.
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 single 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 Rofectan Plus tablet per 10 kg (22 lbs) bodyweight.

Dosage table:

Bodyweight (kg)	**Tablets**
3.0-5.0	½
>5.0-7.5	¾
>7.5-10.0	1
>10.0-15.0	1½
>15.0-20.0	2
>20.0-25.0	2½
>25.0-30.0	3
>30.0-35.0	3½
>35.0-40.0	4
>40.0	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 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 divided tablets.

Do not remove tablets from strip packaging until required for use.

Keep blister in outer carton.

12. SPECIAL WARNING(S)

Special precautions for use in animals:

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.

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

Interaction with other medicinal products and other forms of interaction:

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

compounds can lead to toxicity.

Pregnancy:

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.

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.

For animal treatment only.

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.

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 product should be disposed of in accordance with local requirements. Medicines should not be disposed of via wastewater.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

2 tablets.

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Approved: 17 August 2018