LABELLING AND PACKAGE LEAFLET

A. LABELLING

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

{CARTON FOR PACK SIZES OF 1, 2,4, 5, 6, and 8 TABLETS}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rofectan Plus XL Tablets for Dogs.

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains :175 mg/tablet Praziquantel, 504 mg/tablet Pyrantel Embonate (equivalent to 175 mg pyrantel) and 525 mg/tablet Febantel.

3. PHARMACEUTICAL FORM

Pork Flavoured Tablets.

4. PACKAGE SIZE

1, 2, 4, 5, 6, or 8 tablets.

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

In adult dogs: Treatment of mixed infections with gastrointestinal roundworms, hookworms, whipworms, and tapeworms.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

For oral administration.

Dosage:
1 tablet per 35 kg bodyweight.
This is equivalent to 15 mg febantel, 14.4 mg pyrantel embonate and 5 mg praziquantel per kilo bodyweight. Tablets can be divided into halves if required.

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

Dosage table:

Bodyweight (kg)	Tablets
17.5kg	½
>17.5-35.0 kg	1
>35.0-52.5 kg	1 ½
>52.5-70 kg	2

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

Administration and Duration of Treatment:
Not for use in dogs weighing less than 17.5 kg

The tablets can be given directly to the dog or disguised in food. No starvation is needed before or after treatment.

For routine worm control adult dogs should be treated with a single dose every 3 months.
For the control of Toxocara, nursing bitches should be dosed 2 weeks after giving birth and every two weeks until weaning.

In case of suspected heavy roundworm infestation, please contact your veterinary surgeon for diagnosis and treatment recommendations.

If there is a risk of re-infestation (see package leaflet for Special Warnings), the advice of a veterinarian should be sought regarding the need for and the frequency of repeat administration.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

User warnings

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

Wash hands after use.

Read the package leaflet before use.

If your dog is receiving other medication, check with your vet before using this product.

Do not use simultaneously with other wormers without veterinary advice.

Do not use in animals with a known allergy to any of the ingredients.

Do not use in pregnant dogs, except under veterinary advice.

If signs of disease persist or appear consult a veterinary surgeon.

Do not exceed the stated dose; in the event of an overdose, seek immediate veterinary advice.

Ensure sources of tapeworm re-infestation (fleas and mice) are removed.

10. EXPIRY DATE

EXP {month/year}

Unused half tablets must be used within 14 days.

11. SPECIAL STORAGE CONDITIONS

Do not use after expiry date.

This veterinary medicinal product does not require any special temperature storage conditions.

Keep the blister in the outer carton in order to protect from light.

Each time an unused half tablet is stored, it should be returned to the open blister space and the blister inserted back into the outer carton.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet

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 THESIGHT AND REACH OF CHILDREN"

Keep out 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(S)

Vm 40162/4035

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 XL Tablets for Dogs.,
Praziquantel, Febantel, Pyrantel.

2. NAME OF THE MARKETING AUTHORISATION HOLDER

C&H Generics Ltd

3. EXPIRY DATE

<EXP {month/year}>

4. BATCH NUMBER

<Batch><Lot> {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For Animal Treatment Only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Rofectan Plus XL Tablets for dogs

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

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

Rofectan Plus XL Tablets for Dogs.

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

Each pork flavoured tablet contains 175 mg Praziquantel, 504 mg Pyrantel Embonate (equivalent to 175 mg pyrantel) and 525 mg Febantel.

A yellow coloured oblong tablet with a breakline on both sides.

The tablets can be divided into equal halves.

4. INDICATION(S)

In adult dogs:
For the treatment of mixed infections with roundworms, hookworms, whipworms, and tapeworms of the following species:

Roundworms (Nematodes):
Ascarids (adult and late immature forms): *Toxocara canis*, *Toxascaris leonina*.
Hookworms (adults): *Uncinaria stenocephala*, *Ancylostoma caninum*.
Whipworms (adults)**:** *Trichuris vulpis*.

Tapeworms (Cestodes):
Adult and immature forms of: *Echinococcus* species *(E. granulosus, E. multilocularis), Taenia* species *(T. hydatigena, T. pisiformis, T. taeniformis), Dipylidium caninum*.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.
Do not use simultaneously with piperazine compounds as piperazine may block the action of pyrantel embonate contained in this product. Other worming products may contain piperazine.
Do not use simultaneously with other deworming products without veterinary advice.
Do not exceed the stated dose.

6. ADVERSE REACTIONS

In very rare cases mild 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 side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

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

For oral administration only.

The recommended dose rates are:
1 tablet per 35 kg bodyweight.
This is equivalent to 15 mg febantel, 14.4 mg pyrantel embonate and 5 mg praziquantel per kilo bodyweight.

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

Bodyweight (kg)	Tablets
17.5kg	½
>17.5-35.0 kg	1
>35.0-52.5 kg	1 ½
>52.5-70 kg	2

Not for use in dogs weighing less than 17.5 kg

The tablets can be given directly to the dog or disguised in food. No starvation is needed before or after treatment.

For routine worm control adult dogs should be treated with a single dose every 3 months.
For the control of Toxocara, nursing bitches should be dosed 2 weeks after giving birth and every two weeks until weaning.

In case of suspected heavy roundworm infestation, please contact your veterinary surgeon for diagnosis and treatment recommendations.

If there is a risk of re-infestation (see Special Warnings), 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

Part tablets should be discarded immediately or returned to the open blister until used

Unused half tablet must be used within 14 days.

10. WITHDRAWAL PERIOD

N/A

11. SPECIAL STORAGE PRECAUTIONS

Keep out the sight and reach of children.
This veterinary medicinal product does not require any special temperature storage conditions
Do not use after expiry date stated on the label.
Keep the blister in the outer carton in order to protect from light.
Each time an unused half tablet is stored, it should be returned to the open blister space and the blister inserted back into the outer carton

12. SPECIAL WARNING(S)

Special warnings for each target species:

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.
Dogs should also be prevented from scavenging or hunting as part of measures to prevent tapeworm reinfestation.
If your dog receives other veterinary medicinal products, check with a veterinary surgeon or
pharmacist before using this product.
Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.

Special precautions for use in animals

Do not exceed the stated dose, especially when treating pregnant bitches.

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 the dog, or by adding them to the dog's food, should wash their hands afterwards.

Pregnancy and lactation:

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.
The product may be used in lactating bitches from two weeks after giving birth (see Section 4.9 below).

Interaction with other medicinal products and other forms of interaction:

Do not use simultaneously with piperazine compounds as the anthelmintic effects of pyrantel and piperazine may be antagonized (see 'special warnings for each target species').
Concurrent use with other cholinergic compounds (e.g. neostigmine, propoxur, and bethanechol) can lead to toxicity.

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.

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

15. OTHER INFORMATION

1, 2, 4, 5, 6, or 8 tablets.

Not all pack sizes may be marketed.

Approved 03 February 2021