

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
(CARTON FOR PACK SIZES OF 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 24, 28, 30, 32,
36, 40, 42 and 44 tablets)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MoleCare Cat Wormer 230/20 Film Coated Tablets
pyrantel embonate, praziquantel

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each film-coated tablet contains Pyrantel Embonate 230 mg and Praziquantel 20 mg.

3. PHARMACEUTICAL FORM

Film Coated Tablet

4. PACKAGE SIZE

2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 24, 28, 30, 32, 36, 40, 42, 44 tablets

5. TARGET SPECIES

Cats

6. INDICATION(S)

For the treatment of mixed infections caused by gastrointestinal roundworms and tapeworms.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration

8. WITHDRAWAL PERIOD

N/A

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP month/year

11. SPECIAL STORAGE CONDITIONS

Keep blister in the outer carton.
Discard unused half tablets

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

Read the package leaflet

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

NFA-VPS

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(S)

Vm 40162/4010

17. MANUFACTURER’S BATCH NUMBER

BN {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

(CARTON FOR PACK SIZES OF 48 tablets AND UPWARDS)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MoleCare Cat Wormer 230/20 Film Coated Tablets
pyrantel embonate, praziquantel

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each film-coated tablet contains Pyrantel Embonate 230 mg and Praziquantel 20 mg.

3. PHARMACEUTICAL FORM

Film Coated Tablet

4. PACKAGE SIZE

48, 50, 52, 56, 60, 64, 68, 70, 72, 76, 80, 84, 88, 92, 96, 98, 100, 104, 106, 108, 112, 116, 120, 128, 136, 140, 144, 150, 152, 160, 168, 176, 180, 184, 192, 200, 204, 206, 208, 216, 224, 232, 240, 248, 250, 280, 300, 500 or 1000 tablets

5. TARGET SPECIES

Cats

6. INDICATION(S)

For the treatment of mixed infections caused by gastrointestinal roundworms and tapeworms.

Roundworms: *Toxocaracati*, *Toxascaris leonina*,

Tapeworms: *Dipylidium caninum*, *Taenia taeniaeformis*, *Echinococcus multilocularis*.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Single oral administration. The tablet should be given directly to the cat, but if necessary can be disguised in food. In ascarid infestation, especially in kittens, complete elimination cannot be expected, so a risk of infection for humans can

persist. Repeat treatments should, therefore, be carried out with a suitable roundworm product at 14 day intervals until 2-3 weeks after weaning.

Dosage: 20 mg pyrantel (57.5 mg/kg pyrantel embonate) and 5 mg/kg praziquantel. This is equivalent to 1 tablet per 4 kg bodyweight.

Body weight	tablets
1.0 - 2.0 kg	½
2.1 - 4.0 kg	1
4.1 - 6.0 kg	1 ½
6.1 - 8.0 kg	2

8. WITHDRAWAL PERIOD

N/A

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP month/year

11. SPECIAL STORAGE CONDITIONS

Keep blister in the outer carton.
Discard unused half tablets

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

Read the package leaflet

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

NFA-VPS

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(S)

Vm 40162/4010

17. MANUFACTURER’S BATCH NUMBER

BN {number}

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS
{NATURE/TYPE}**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MoleCare Cat Wormer 230/20 Film Coated Tablets
pyrantel embonate, praziquantel

2. NAME OF THE MARKETING AUTHORISATION HOLDER

C & H Generics Ltd

3. EXPIRY DATE

EXP month/year

4. BATCH NUMBER

BN {number}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

PACKAGE LEAFLET FOR:

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

MoleCare Cat Wormer 230/20 Film Coated Tablets
pyrantel embonate, praziquantel

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

Each film-coated tablet contains Pyrantel embonate 230 mg and Praziquantel 20 mg. A white to off white round, biconvex coated tablet with a breakline on one side and plain on the other side.

4. INDICATION(S)

For the treatment of mixed infections caused by the following gastrointestinal roundworms and tapeworms:

Roundworms: *Toxocara cati*, *Toxascaris leonina*,

Tapeworms: *Dipylidium caninum*, *Taenia taeniaeformis*, *Echinococcus multilocularis*.

5. CONTRAINDICATIONS

Do not use simultaneously with products containing piperazine.

Do not use in kittens less than 6 weeks of age.

Do not use in animals with known hypersensitivity to the active substances or to any of the excipients.

6. ADVERSE REACTIONS

Mild and transient digestive tract disorders such as hypersalivation and/or vomiting and mild and transient neurological disorders such as ataxia may occur in very rare cases.

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

- very common (more than 1 in 10 animals displaying adverse reaction(s) 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

Cats

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

Dosage: The recommended dose is 20 mg pyrantel (57.5 mg/kg pyrantel embonate) and 5 mg/kg praziquantel. This is equivalent to 1 tablet per 4 kg bodyweight.

Body weight	tablets
1.0 - 2.0 kg	½
2.1 - 4.0 kg	1
4.1 - 6.0 kg	1 ½
6.1 - 8.0 kg	2

Administration and duration of treatment: Single oral administration. The tablet should be given directly to the cat, but if necessary, can be disguised in food. In ascarid infestation, especially in kittens, complete elimination cannot be expected, so a risk of infection for humans can persist. Repeat treatments should, therefore, be carried out with a suitable roundworm product at 14 day intervals until 2-3 weeks after weaning.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD(S)

N/A

11. SPECIAL STORAGE PRECAUTIONS

Do not use after the expiry date stated on the blister and carton. Discard unused half tablets. Keep blister in outer carton.

12. SPECIAL WARNING(S)

Special precautions for use in animals

Do not use during pregnancy but may be used during lactation. After doses higher than 5 times the recommended dose, signs of intolerance such as vomiting have been observed. Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class. Fleas serve as intermediate hosts for one common type of tapeworm –*Dipylidium caninum*. Tapeworm infestation is certain to reoccur unless control of intermediate hosts such as fleas, mice, etc. is undertaken.

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 a cat or adding them to the cat'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 (e. g. experts or institutes of parasitology). If the cat has visited areas where *Echinococcus spp.* are prevalent, a veterinarian should be consulted.

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

Ask your veterinary surgeon/pharmacist 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 2021

15. OTHER INFORMATION

NFA - VPS

Vm 40162/4010

2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 24, 28, 30, 32, 36, 40, 42, 44, 48, 50, 52,
56, 60, 64, 68, 70, 72, 76, 80, 84, 88, 92, 96, 98, 100, 104, 106, 108, 112,
116, 120, 128, 136, 140, 144, 150, 152, 160, 168, 176, 180, 184, 192, 200,
204, 206, 208, 216, 224, 232, 240, 248, 250, 280, 300, 500 or 1000 tablets.

Not all pack sizes may be marketed.

Approved: 16/12/21

