{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

Milaxyn 230/20mg Flavoured Film Coated Tablets.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

3. PACKAGE SIZE

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

4. TARGET SPECIES

Cats.

5. INDICATION(S)

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

6. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

For oral administration.

1 tablet per 4 kg bodyweight.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

EXP {month/year}
Discard unused half tablets.

9. SPECIAL STORAGE PRECAUTIONS

Keep blister in outer carton.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. 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

14. MARKETING AUTHORISATION NUMBERS

Vm 40162/5000

15. BATCH NUMBER

16. SPECIAL WARNING(S), IF NECESSARY

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

Disposal: read the package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

NFA-VPS

Veterinary medicinal product subject to prescription.
To be administered by a veterinary surgeon or under their direct responsibility.

{CARTON FOR PACK SIZES OF 48 TABLETS, AND UPWARDS}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milaxyn 230/20mg Flavoured Film Coated Tablets.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

3. 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

4. TARGET SPECIES

Cats.

5. 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.*

6. ROUTES OF ADMINISTRATION

Dosage: 20 mg/kg 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

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.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

EXP {month/year}
Discard unused half tablets.

9. SPECIAL STORAGE PRECAUTIONS

Keep blister in outer carton.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. 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

14. MARKETING AUTHORISATION NUMBERS

Vm 40162/5000

15. BATCH NUMBER

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

Disposal: read the package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

NFA-VPS

Veterinary medicinal product subject to prescription.
To be administered by a veterinary surgeon or under their direct responsibility.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS BLISTER FOIL TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milaxyn 230/20mg Flavoured Film Coated Tablets.

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

Pyrantel embonate 230 mg, Praziquantel 20 mg.

3. BATCH NUMBER

4. EXPIRY DATE

EXP {month/year}

5. NAME OF THE MARKETING AUTHORISATION HOLDER

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

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For Animal Treatment Only.

PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milaxyn 230/20mg Flavoured Film Coated Tablets for cats.

2. COMPOSITION

Each film coated tablet contains:

Active substances:
Pyrantel embonate *230 mg*
Praziquantel *20 mg*

A white to off white round, biconvex coated tablet with a breakline on one side and plain on the other side.
The tablets can be divided into 2 equal parts.

3. TARGET SPECIES

Cats

4. INDICATIONS FOR USE

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 cases of hypersensitivity to the active substances or to any of the excipients.

6. SPECIAL WARNING(S)

For Animal Treatment Only
Special precautions for safe use in the target species:
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.
Parasitic resistance to a certain class of anthelmintics can occur after frequent and

repeated use of an anthelmintic from this 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 immediately and show the package leaflet or label 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.
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.
Pregnancy and lactation:

Do not use during pregnancy but may be used during lactation.

Overdose:

After doses higher than 5 times the recommended dose, signs of intolerance such as vomiting have been observed.

7. ADVERSE EVENTS

Target species: Cats

Very rare *(<1 animal / 10,000 animals treated, including isolated reports):*	*Mild and transient digestive tract disorders such as hypersalivation and/or vomiting and mild and transient neurological disorders such as ataxia may occur.*

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system {national system details}.
{national system details}". https://www.gov.uk/report-veterinary-medicine-problem

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

Dosage

The recommended dose is: 20 mg/kg 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

Keep out of the sight and reach of children.
Keep blister in outer carton.

Do not use this veterinary medicinal product after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.
Discard unused half tablets.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Ask your veterinary surgeon/pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

Medicines should not be disposed of via wastewater.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

NFA-VPS

Veterinary medicinal product subject to prescription.
To be administered by a veterinary surgeon or under their direct responsibility

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 40162/5000

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

November 2022

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

16. CONTACT DETAILS

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

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

17. OTHER INFORMATION

The blisters are packed into cartons containing either:

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 08 December 2022