

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

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, 42,44, 48 TABLETS AND ABOVE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milaxyn 230/20mg Flavoured Film Coated Tablets for Cats

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PACKAGE SIZE

2, 4, 5, 6, 8, 10, 12, 14, 16, 18, 20, 24, 28, 30, 32, 36, 40, 42, 44, 48 tablets and above.

4. TARGET SPECIES

Cats.

5. INDICATIONS

For products not subject to veterinary prescription:

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

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Unused half tablets should be discarded.

9. SPECIAL STORAGE PRECAUTIONS

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 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 40162/3000

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Blister foil text}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milaxyn 230/20mg Flavourised Film-Coated Tablets



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

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

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

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: Pyrantel embonate 230 mg (equivalent to 79.79mg of Pyrantel) 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.

The tablets can be divided into two 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 leonine*,

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

5. Contraindications

Do not use simultaneously with piperazine compounds.

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 warnings

Special warnings:

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.

If there is a risk for re-infestation, the advice of a veterinarian should be sought regarding the need for and the frequency of repeat administration in cats. Local epidemiological information and the living conditions of the cat should be taken into account. It is also important to remove sources of possible re-infection such as fleas and mice.

Parasitic resistance to a certain class of anthelmintics can occur after frequent and repeated use of an anthelmintic from this class.

Special precautions for safe use in the target species:

As the tablets are flavoured, they should be stored in a safe place out of the reach of animals. Animals in a poor condition or heavily infested, which can be manifested by symptoms such as diarrhoea, vomiting, presence of parasites in faeces and vomit, poor hair condition, should be examined by a veterinarian prior to the product administration. For severely debilitated or heavily infested cats, use only according to a benefit/risk assessment by the responsible veterinarian.

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 the 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.

Pregnancy and lactation:

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

Interaction with other medicinal products and other forms of interaction:

Do not use simultaneously with products containing piperazine.

Overdose:

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

Special restrictions for use and special conditions for use:

<To be completed nationally>

<ES: To be administered by a veterinary surgeon or under their direct responsibility.>

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.

7. Adverse events

Target species: Cats.

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	<i>Digestive tract disorders (hypersalivation and/or vomiting) Neurological disorders (ataxia).</i>
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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 or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, routes and method of administration

Oral use.

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

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

9. Advise on correct administration

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

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out the sight and reach of children.

Shelf-life after first opening the immediate packaging: use immediately.

Unused half tablets must be discarded.

Keep the 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.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater <or household waste>.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

For UK only:

Medicines should not be disposed of via wastewater.

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

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

13. Classification of veterinary medicinal products

<to be completed nationally>

14. Marketing authorisation numbers and pack sizes

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.

15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

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

Chanelle Pharmaceuticals Manufacturing Ltd
Dublin Road
Loughrea
Co. Galway
Ireland

Local representatives <and contact details to report suspected adverse reactions>:

To be completed nationally

Approved 08 December 2022

A handwritten signature in black ink, appearing to read "Hunter.", is positioned below the approval date.